THE DEVELOPMENT OF VALIDATED GUIDELINES THAT CONTRIBUTE TO THE PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE IN SOUTH AFRICA

by

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DECLARATION

By submitting this dissertation electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

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ABSTRACT

Introduction

Substandard care resulting in billions of rand pay-outs due to malpractice litigation remains a challenge in nursing practice.

Purpose

To develop validated guidelines that contribute to the prevention of malpractice litigation in nursing practice in South Africa.

Research questions

What are the contributing factors that lead to adverse events in nursing care?

What are the validated guidelines that can be developed to contribute to the prevention of malpractice litigation in nursing practice in South Africa?

Methodology

The study was conducted in three phases:

Phase 1:

A retrospective audit of adverse events using a descriptive quantitative design with Pearson Chi-Square test, CI 95%, $p \leq 0.05$ was conducted on 203 malpractice litigation cases from the Eastern Cape and Gauteng public healthcare sectors.

Phase 2:

A comparative statistical analysis was carried out to compare and contrast adverse events - 122 malpractice litigation cases audited by two master's students in the Western Cape and Gauteng private sector with the phase 1 litigated cases.

Phase 3:

Nursing practice guidelines were developed using the identified adverse events that contributed to adverse events by applying the WHO guidelines and expert validation using the Delphi method.

Results:

Phase 1:

A key finding - Out of 143 cases admitted to labour wards 135 babies had cerebral palsy in this study.

Adverse events contributing factors:

- **Nursing clinical management (87% of adverse events):**
  Assessment; diagnosis; planning; implementation and evaluation including observations; tests; interpretation and documentation; as well as clinical management.

- **Behavioural problems (12.3% of adverse events):**
  Not following guidelines (91.6%), non-response to clinical manifestations (79.4%), accumulation of omissions (49.8 %), an accumulation of errors (41.8 %), administering and incorrect treatment (16.0 %).

- **Organisational and administrative factors**
  Lack of knowledge (28.9 %), organisational (23.7%), system failure (21.5, lack of training (19.4 %) %), lack of supervision (17.5 %) and administrative (6.5%).

Phase 2:

- A total of 325 trial bundles were audited - 122 by two master's students in private and 203 in public healthcare by a PhD student. Statistical differences showed that 76.0% of patients' quality of life were affected (p=0.01).
- Statistically, it was shown that patients were more likely to die in the private sector (p=0.01) and more likely to be disabled in the public sector (p=0.01).
- No statistical difference was identified in clinical management between private and public healthcare sectors (p= 0.27).
- The private healthcare sector was more likely to have adverse events, due to organisational and administrative problems.
- The public healthcare sector was more likely to have poor resources with a critical shortage of doctors and nurses.

Phase 3:

- Guidelines were developed by applying the WHO guideline development process and validated, applying the Delphi method.
- One hundred and forty-four guidelines were developed, validated and grouped into Clinical Management, Human Behaviour, and Organisational factors.
- National and international experts participated in the validation process.

Ethical considerations

Approval was obtained from Stellenbosch University (N16/02/027A).

Recommendation

The validated guidelines developed in the study should be further tested and implemented in South Africa to contribute to the prevention of the escalating malpractice litigation in nursing practice.

OPSOMMING

Inleiding

Substandaard sorg bly ‘n uitdaging vir die verpleegpraktyk, wat aanleiding gee tot die uitbetaling van miljarde rande weens wanpraktyk litigasie.

Doelwit

Die doel is om gevalideerde riglyne te ontwikkel wat sal bydra tot die voorkoming van wanpraktyk litigasie in die verpleegpraktyk in Suid-Afrika.

Navorsingsvrae

1. Wat is die bydraende faktore wat aanleiding gee tot ongunstige gevalle in die verpleegpraktyk?
2. Wat is die gevalideerde riglyne wat ontwikkel kan word wat sal bydra tot die voorkoming van wanpraktyk litigasie in die verpleegpraktyk in Suid Afrika?

Metodologie

Die navorsingstudie is in drie fases gedoen.

Fase 1:

‘n Retrospektiewe oudit van ongunstige gebeure deur ‘n beskrywende kwantitatiewe ontwerp met behulp van Pearson se Chi-Kwadraat toets, CI 95%, $p \leq 0.05$ is op 203 wanpraktyk litigasie gevalle van die Oos-Kaap en Gauteng openbare gesondheidsorg sektore gedoen.

Fase 2:

‘n Vergelykende statistiese analise is uitgevoer om die ongunstige gevalle te vergelyk en te kontrasteer – 122 wanpraktyk litigasie gevalle is deur twee meestersgraad studente in die Wes-Kaapse en Gauteng private sektor deur fase 1 se gelitigeerde gevalle geoudit.

Fase 3:

Riglyne vir die verpleegpraktyk is ontwikkel, deur gebruik te maak van die geïdentifiseerde ongunstige gevalle wat gelei het tot ongunstige gevalle, deur die riglyne van die WGO, asook die deskundige validasie van die Delphi-metode toe te pas.

Resultate

Fase 1:

‘n Sleutelbevinding – verloskunde is in ‘n krisis met 135 gevalle van serebrale verlamming uit die 143 gevalle opgeneem in kraamsale.

Bydraende faktore wat lei tot ongunstige gevalle:

- Kliniese Verplegingsbestuur (87% van ongunstige gevalle):
  Beraming; diagnose; beplanning; implementering en evaluering ook ingesluit observasies, toetse; interpretasie en dokumentasie; asook kliniese bestuur.
- Gedragsprobleme (12.3% van ongunstige gevalle):
  Geen toepassing van riglyne nie (91.6%), geen respons op kliniese manifestasies nie (79.4%), opeenhoping van weglatings (49.8%), ‘n opeenhoping van foute (41.8%), en toediening van foutiewe behandeling (16.0%).
- Organisatoriese en administratiewe faktore
  Gebrek aan kennis (28.9%), organisatories (23.7%), stelselfout (21.5%), gebrek aan opleiding (19.4%), gebrek aan toesig (17.5%) en administratief (6.5%).

Fase 2:

- ‘n Totaal van 325 proefbundels is geoudit - 122 deur twee meestersgraad studente in private, en 203 in openbare gesondheidsorg sektore deur ‘n PhD student. Statistiese verskille toon dat 76.0% van die lewenskwaliteit van pasiënte is geaffekteer (p=0.01). Dit is statisties bewys dat ‘n pasiënt meer waarskynlik sal sterf in die privaatsektor (p=0.01) en meer waarskynlik gestremd sal wees in die openbare sektor (p=0.01).
- Geen statistiese verskil is geïdentifiseer met betrekking tot kliniese bestuur tussen private en openbare gesondheidsorg sektore nie (p = 0.27).
- Die private gesondheidsorg sektor is meer waarskynlik geneig tot ongunstige gevalle, weens organisatoriese en administratiewe probleme.
- Die openbare gesondheidsorg sektor is meer waarskynlik geneig tot ‘n tekort aan hulpbronne met ‘n groot tekort aan dokters en verpleegsters.

Fase 3:

- Riglyne is ontwerp deur die toepassing van die WGO se riglyn-ontwikkelingsproses en gevalideer deur die gebruik van die Delphi-metode.
- Een honderd vier-en-veertig riglyne is ontwikkel, gevalideer en gegroepeer in Kliniese Bestuur, Menslike Gedrag en Organisatoriese faktore.
- Nasionale en internasionale deskundiges het aan die geldigverklaringsproses deelgeneem.

Etiese oorweging

Goedkeuring is verkry van die Universiteit van Stellenbosch (N16/02/027A).

Aanbeveling

Die gevalideerde riglyne wat in hierdie studie ontwikkel is, behoort verder getoets en geïmplementeer te word in Suid-Afrika, om by te dra tot die voorkoming van die toenemende wanpraktyk litigasie in die verpleegpraktyk.

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ACRONYMS ABBREVIATIONS

ANA	American Nurses Association
ART	Antiretroviral Therapy
COHSASA	Council for Health Service Accreditation in Southern Africa
CPD	Continuing Professional Development
DOJCD	The acting Chief Litigation Officer of the Department of Justice and Constitutional Development
ECP	Eastern Cape Province
ECG	Electrocardiogram
ENA	Enrolled Nurse
EN	Enrolled nursing Assistant
GP	Gauteng Province
GDG	Guideline Development Group
GDP	Gross Development Product
GRM	Generic Reference Model
HE	Health Establishment
HPCSA	Health Professions Council of South Africa
IBM	International Business Machines
ICPS	International Classification for Patient Safety
ICU	Intensive Care Unit
NCS	National Core Standards
NHI	National Health Insurance
NRF	National Research Foundation
OHSC	Office of Health Standards Compliance
PhD	Doctor of Philosophy in Nursing
RN	Registered Nurse
SAC	Safety assessment code
SANC	South African Nursing Council
SPSS	Statistical Package for the Social Sciences (SPSS)
WHO	World Health Organisation.

OPERATIONAL DEFINITIONS

The following terms are defined for this study, and the terms will be used as defined:

- Adverse event: The WHO (2009:3) describes an adverse event as an event that may result in a health hazard to a client that is receiving healthcare services in the Health Establishments.
- Event: It is a good or harmful act that may involve a patient (WHO, 2007:4).
- Expert: A practitioner that is able to grasp knowledge easily and successfully at problem-solving without knowing the origin of the problem, Benner (1984) in Hill (2010:1).
- Hazard: It is referred to as a source of potential damage or harm to a client (WHO, 2009:14).
- Healthcare: It is the organised provision of medical services that are rendered to the community members (WHO, 2007:5).
- Health Establishments (HEs): It is a public or non-profit facility within a state that provides healthcare-related service (OHSC, 2016).
- Incident: It is an event that can occur and disturb the organised plan to provide health care, examples include falls, medication, clinical care or nutrition (WHO, 2009:14).
- Litigation: A legal dispute that involves court proceedings and a court decision can be taken (Oosthuizen, 2014:11).
- Malpractice litigation trial bundles: The documents that are well organised, that are prepared for use in a court of law either by the judge or witness. For reference, the documents have page numbers (Legal Technology, 2012: 1).
- Malpractice: It is an acceptable act or an instance of incompetence by a healthcare professional which may lead to adverse event occurrence (The Joint Commission, 2003: 22).
- Near-miss incident resulting in no harm: The incident that provides a learning experience about the challenges that are affecting quality patient care (WHO, 2009:7).
- Negligence: It is a substandard care that may be provided to the health service user and may result in health risk (Marzuki, Wichaikhum & Nantsupawat, 2013:58-60).
- Patient safety: A state of protection from health hazards or risks and it depends on the systems that are in place in the HE (Dekker, 2016:1).
- Patient: Is a person who is under medical care (Shiel, 2010.1).
- Quality of care: An expected standard of care which is based on set standards, the regulations act and guidelines.

- The following outcome standards are indicators of quality of care: patient satisfaction, death or illness (Mitchell, 2013: 513-518.).
- Safety assessment code (SAC) (SA Health Risk Management Framework, nd) An analysis of the severity of the outcome of an incident as applied by the SAC classification system. The severity is assessed using a matrix of actual or potential impact to the patient or organisation, and the likelihood of recurrence according to the SA Health Risk Management Framework (South Australia, 2011:2).

CHAPTER 1: FOUNDATION OF THE STUDY

1.1 INTRODUCTION

The quality and safety of patients at Health Establishments are being compromised by various factors, such as the burden of diseases and the shortage of resources (James, 2013:122-128). Despite the measures being introduced at Health Establishments (HEs) to improve patient safety, adverse events still occur as these measures are not as reliable as envisaged to be (Chassin & Loeb, 2014:1). The role of nursing mismanagement and its contribution to adverse events that lead to malpractice litigation in nursing practice have not been sufficiently studied in South Africa.

The researcher is a PhD student at Stellenbosch University and one of three students who participated in an ongoing larger study entitled “Retrospective Audit Analysis of Malpractice Litigation Cases in Nursing Practice in South Africa” in which malpractice litigation in Nursing Practice is being investigated in South Africa (N16/02/027). Two master’s degree students completed an audit of malpractice litigation in the private healthcare sector and the PhD student completed a study in the public healthcare sector.

Chapter 1 covers the background to the study, its rationale, research questions, problem statement, purpose, an overview of the research methodology and ethical considerations used in this study.

This study aims to develop and validate guidelines that contribute to the prevention of adverse events, which may have led to malpractice litigation in nursing practice in South Africa.

1.2 RATIONALE

Nurse practitioners need more than just an understanding of patient safety, but should display a commitment to quality patient care through adherence to set standards and guidelines. Safe and quality patient care includes a complete assessment, diagnosis and management (Gcawu, 2012:24). Quality care is compromised because avoidable adverse events are common, which have serious consequences for patients and health practitioners (Oosthuizen, 2014:11). According to Carrier, Reschovsky, Mello, Mayrell and Katz (2010:1585-1592) some health professionals believe that existing circumstances, such as unclear practice guidelines and clinical negligence compromise health care, which consequently may lead to litigation.

Lack of equipment in any HE may lead to health risks and inability of the nurses to perform their duties according to acceptable standards (Sherwood, 2015:734). Management and leadership responsibilities include ensuring the proper distribution and utilisation of resources in their HEs

(Hitchins, 2014:4). Safe patient care cannot be provided when there are challenges, such as inadequate resources.

Some patients that are admitted to the Health Establishments (HEs) are at risk of medical and nursing practice negligence not related to their actual healthcare problem. Vulnerable patients are exposed to conditions which are detrimental to their health (Oosthuizen, 2014:11). According to New, Goodridge, Kappel, Groot and Dobson (2019: 199) the biggest concern patients have when admitted to the HEs is patients' safety. When negative experiences or trauma results from safety incidents, the trust that the patients may have had might be jeopardized. Malherbe, (2013:83-88) confirmed that 2 403 complaints that were received by the Health Professions Council of South Africa (HPCSA) between April 2011 and March 2012 included adverse events related to refusal to treat patients, misdiagnoses and practising outside the scope of practice.

The South African health system faces numerous challenges, with a larger population dependent on a "dysfunctional" public healthcare sector. Adverse events i.e. harm to patients are indicators of poor safety in healthcare and may be attributed to latent factors such as poor supervision, shortage of staff, unskilled staff, lack of knowledge and poor communication (James, 2013:122-123). Healthcare outcomes for the patient may include disease, injury and /or disability, which is also impacted by the duration, severity and availability of resources. The severity of adverse events ranges between extreme to minor to insignificant. Examples of adverse events include the loss of a limb, developing a nosocomial infection, disability or death.

The National Minister of Health, Dr Aaron Motsoaledi indicated in 2015 that South Africa is faced with a crisis of an increase in medical malpractice litigation, not only noted in the public healthcare sector but the private healthcare sector as well (Sapa | 09 March 2015). For the financial year 2012-2013, the Department of Health in the Eastern Cape Province was faced with claims, due to negligence to the value of R1.28 billion, while five years earlier lawsuits amounted to R216-million (Child, 2014:7). In 2012 the highest claim yet in South Africa paid out almost R24 million on behalf of a member (South African Law Reform Commission, 2017:14). The acting Chief Litigation Officer of the Department of Justice and Constitutional Development (DOJCD), the principal amounts paid out for litigation on behalf of the Department of Health by the offices of the State Attorney amounted to a sum of R 95 531 132.44 during the years 2010/2011 to R 498 964 916.72 in 2013/2014. Contingent liabilities for medical malpractice was R40 923 535 000 for the financial year 2015/2016 (South African Law Reform Commission, 2017:17).

In their study on staffing in nursing, Cho, Hwang and Kim (2008: 322-330) identified that for every additional patient per professional nurse, there was an association of a 9% increase in the odds of dying. Hoogervorst-Schilp, Langelaan, Spreeuwenberg, De Bruijne and Wagner (2015:1) also

found in a study conducted in Dutch hospitals that 95% of the patients stayed longer in the HEs due to adverse events occurring which included nosocomial infections.

Duarte, StippI, Da SilvaI and De OliveiraI (2015: 136-154), conducted a study in Brazil on scientific publications about adverse events in nursing care, in adult hospitalised patients. The study revealed that the main cause of malpractice litigation in nursing practice was poor treatment techniques (87.6 %). At the Porto Alegre Surgical Clinic, a study conducted in 2009 revealed 264 adverse events related to loss of catheters, tubes, drains and falls from beds (18.56%). A study done in Sao Paulo revealed that poor nursing care resulted in the development of pressure sores in 69.2% of patients.

Measures to improve patient safety resulted in 1.3 million fewer patient harms, 50 000 lives were rescued, and a reduction in $12 billion in health spending avoided in United States of America due to a reduction in hospital-acquired conditions between 2010 and 2013 (United States of America, Department of Health & Human Services, 2014:1). Despite the challenges encountered in nursing practice, healthcare providers remain accountable to their duty of care to patients (Stellenberg & Dorse, 2014:5). Nurses who are known to be 24-hours at the bedside of patients should be vigilant, competent, skilled and knowledgeable about the care they deliver. Weld and Garmon Bibb (2009:16) emphasise that “nurses must confront the fact that they now owe a higher duty of care to their patients, and by extension, are more exposed to civil claims for negligence than ever before...”

The health organisation has a responsibility to engage in strategies of improving quality and safer care. In a healthcare organisation where patient safety norms are practised and under conducive working conditions, nurses become committed to improving quality patient care (Mathibe-Neke, 2015:6). Further, the integral role of the nurses is in providing safer healthcare practices as a component of the multidisciplinary team. National Academy for State Health Policy (NASHP) traced and monitored state progress on the patient-safety issue, followed by a provision of support through reports, technical assistance, a patient safety discussion group, patient safety toolbox, conferences and workshops (Hanlon et al.,2015:17).

Lack of research and barriers to reporting of near misses and nursing negligence suggest the need for further research (Vrbnjak, Denieffe, O’Gorman & Pajnkihar, 2016: 162-178). Quality patient care should be the core business in nursing practice. Fortunately, there are meticulous ways and measures available to improve and measure patient care, and these measures include data from a patient's record or operational processes (Duarte et al., 2015: 136-154). The purpose of quality patient care is to make these measures more reliable, uniform and helpful to consumers in making healthcare choices (Wisconsin Hospital Association, 2015:4).

Nurses are ethically and legally bound to provide safe patient care. The South African Nursing Council has introduced a Code of Ethics for Nurse Practitioners in South Africa, which needs to be adhered to by nurses in their practice. The Code of Ethics is a binding document which entails content that the nurses must comply to with their practice and ethical decision making (South African Nursing Council, 2013). The Bill of Rights, as described in the Constitution Act, 1996 (Act No 108 of 1996), supports this code in respecting the rights of all human beings. Nursing professionals are expected to practise within the ethical codes of the governing body. According to Kangasniemi, Pakkanen and Korhonen, (2015:1744-1757) professional ethics encompass principal behavioural aspects which are grounded on moral values, judgement, responsibility and accountability.

Escalated malpractice litigation and pay-outs have led the researcher to conduct this study to identify contributing factors that compromise patient safety in nursing care which may result in adverse events that may lead to malpractice litigation. The researcher identified that a need exists to develop and validate guidelines that will contribute to the prevention of malpractice litigation in nursing practice in South Africa.

1.3 PROBLEM STATEMENT

The researcher in her midwifery clinical practice in a public health hospital observed that a deficit existed in material and human resources, and the unavailability and poor implementation of guidelines which affected the patient safety delivery. She also observed that in some hospitals in the Eastern Cape Province (ECP), patients were sharing a bed in maternity wards, which disregarded the fact that one of the patients had been diagnosed with pre-labour rupture of membranes. In some labour wards, there were no screens, resulting in patients' deliveries being conducted without screening, thereby violating the patient's privacy. In such situations, some patients preferred to deliver in the toilet where they had privacy. According to Mitchell (2013:513-518) in one of the public hospitals in the Eastern Cape, 29 neonates died because of a lack of adherence to infection control measures.

Nurses play a critical role in ensuring a safe patient care environment (National Association of Neonatal Nurses, 2016: 6). However, nurses are faced with challenges which affect their efforts in providing quality patient care, which frequently result in compromising ethical and moral values. Furthermore, it is asserted that patient safety should not be compromised at any point in time, but that safety practices should always be in place (Mitchell, 2013:513-518).

As described the researcher has shown that there are numerous factors in HEs such as organisational, behavioural and clinical management that may lead to adverse events resulting in malpractice litigation. Malherbe (2013:83-84) reported that malpractice litigation has become

a serious concern in South Africa and maybe the destruction of health services if not addressed urgently. Claims which exceeded R1 million increased by nearly 550%, while claims over R5 million increased by 900% in five (5) years.

Against this background the researcher identified that there was a gap in scientific knowledge about guidelines which might contribute to the prevention of adverse events leading to malpractice litigation in nursing practice.

1.4 PURPOSE OF THE STUDY

To develop and validate nursing practice guidelines that will contribute to the prevention of adverse events that culminate in nursing malpractice litigation in public and private healthcare sectors in South Africa

1.5 RESEARCH QUESTIONS

The following study questions were set to achieve the study purpose:

- What are the contributing factors that lead to adverse events in nursing care?
- What are the validated guidelines that can be developed to contribute to the prevention of malpractice litigation in nursing practice in South Africa?

1.6 RESEARCH OBJECTIVES

1. To conduct a retrospective audit of adverse events resulting in malpractice litigation described in trial bundles from cases in the public healthcare sector in the Gauteng and Eastern Cape provinces.
2. To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces.
3. To use the results of objectives 1 and 2 to develop a set of guidelines that will contribute to the prevention of nursing malpractice litigation in South Africa.
4. To validate the developed guidelines using the Delphi method and publish the results.

1.7 METHODS OVERVIEW

This study was conducted in three phases and a brief overview of the phases is given below:

- Phase 1: The PhD student applied a descriptive quantitative research design to conduct a retrospective audit of adverse events which had led to malpractice litigation in the public healthcare sector in the Gauteng and Eastern Cape provinces.

- Phase 2: A comparative analysis was completed on the results of adverse events that led to malpractice litigation in the private healthcare sector completed by two masters' degree students and the public health sector completed by the PhD student.
- Phase 3: A draft set of guidelines which may contribute to the prevention of malpractice litigation in nursing in South Africa was developed by applying the WHO development process and the guidelines were validated by applying the Delphi method.

The phases are extensively described in chapter 4.

1.7.1 Phase 1: Objective 1 Research methodology

A brief description is provided in chapter 1 and more detail in chapter 4.

A descriptive quantitative research design was used to conduct a retrospective audit of adverse events, which led to malpractice litigation in the public healthcare sector in the Gauteng and Eastern Cape provinces with the following objectives to:

- complete an audit of the nursing process documents in the trial bundles
- determine the principal incident types that were associated with adverse events involving nursing practitioners. The scope of practice, draft regulation R786 of 2013 based on the Nursing Act, 2005 (Act No. 33 of 2005) was used to guide this objective.
- determine the factors that were associated with adverse events involving nursing practitioners
- identify other members of the health service team that were associated with these adverse events. The scope of practice of other healthcare professionals, policies and guidelines guided the researcher.
- determine the severity of the adverse events as defined by the Safety assessment code (SAC) (SA Health Risk Management Framework, nd).

1.7.1.1 Hypotheses

The following hypotheses were set for objective 1 of phase 1:

H1: There are differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng, and the Eastern Cape provinces was accepted.

H0: There are no differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces was rejected

1.7.1.2 Population and sampling

The total population of available trial bundles which occurred over eleven years, 2006-2016 from each province was included in the study. A power analysis was completed identifying that 200 cases brought against the public healthcare sector which is described in more detail in paragraph 4.3.4.

1.7.1.3 Sampling criteria

Sample criteria were completed cases which occurred over 11 years, 2006-2016 which occurred in the public healthcare sector of the Gauteng and Eastern Cape provinces.

1.7.1.4 Pilot study

A pilot study was conducted using an opportunistic sample which included n=42 (10.5%) trial bundles obtained from Gauteng, Western Cape and Kwa-Zulu Natal provinces for the main study of 400 trial bundles. More detail is described in chapter 4.

1.7.1.5 Reliability and validity

1.7.1.5.1 Reliability

The test-retest reliability test used in the pilot study identified minor corrections requiring adaptations.

1.7.1.5.2 Validity

The content validity approach was used to determine the extent to which all major elements of the construct were measured

Face validity of the study was assessed with the guidance of the experts in the field of quality assurance, specifically the quality and safety of patient care.

1.7.1.6 Instrumentation (Annexure 1)

A validated audit instrument consisting of six sections based on objectives 1 and 2 of the study was applied, as described in chapter 4. A team of researchers who are experts in the field of quality assurance specifically quality and safety of patient care were involved in the development of the data collection instrument. This is detailed in chapter 4.

The audit instrument was designed for the main study “Retrospective Audit Analysis of Malpractice Litigation Cases in Nursing Practice in South Africa” in which malpractice litigation in Nursing practice was investigated in South Africa (N16/02/027. The duration of the development of the audit instrument was almost eight months. This instrument was developed for both public and private sectors. The detail pertaining to the instrument is described in chapter 4.

1.7.1.7 Data collection

The researcher collected the data using the audit instrument that was developed for the purpose of this study.

1.7.1.8 Analysis of data

Completion of the research study enabled the researchers to explore the underlying factors which led to the adverse event and malpractice litigation. The descriptive statistics and comparative statistics to determine any statistical associations were applied in this study.

1.7.2 Phase 2: Objective 2

This phase was aligned to objective 2 of this study**:** To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces.

1.7.2.1 Hypotheses

Hypotheses set for this phase are:

H1: There are statistical differences between the public and private analysis of adverse events which led to malpractice litigation in nursing practice **were accepted**

H0: There are no statistical differences between the public, and private analysis of adverse events which led to malpractice litigation in nursing practice **were rejected**.

1.7.2.2 Comparative analysis

Comparative statistical analysis was applied to compare the data that were obtained through the studies conducted in the public sector by the PhD student and private sector conducted by two master's students. The data of the studies were merged for the purpose of this objective.

1.7.3 Phase 3: Objectives 3 and 4

This phase was based on developing and validating a set of guidelines which may contribute to the prevention of nursing malpractice litigation in South Africa. The guidelines were developed by using the WHO development process (WHO, 2012: 11). The development was descriptive, based on the results obtained from a comparative analysis that was completed in phase 2 of this study. This is further described in paragraph 4.5.3.1 of chapter 4. The drafted guidelines were validated by applying the Delphi method (Grove et al., 2016:358). The validation process is described in paragraph 4.5.4.2 chapter 4.

1.8 SIGNIFICANCE OF THIS RESEARCH STUDY

This study may have a wide impact on South Africa's national health and provincial budgets, as billions of rand are currently being paid out to malpractice litigation. The escalating number of malpractice litigation may decrease thus saving the country billions of rand which could be used to improve the service delivery in the public and private healthcare sectors. The study may also have an impact on strengthening clinical management, organisational management, administrative management and behavioural management. The study may be a foundation for further research in nursing practice. Further discussion of the study is discussed in chapter 8.

1.9 ETHICS CONSIDERATION

Ethics approval was obtained from the Faculty of Medicine and Health Sciences at Stellenbosch University which included a waiver of consent that allowed the researcher to audit the trial bundles without the plaintiffs' or defendants' permission (Ethics Committee approval number N16/02/027A - Annexure 2). All other ethics considerations were adhered to, as explained in chapter 4.

1.10 SUMMARY

This chapter provides the rationale for the study, problem statement, the purpose, research objectives, a brief explanation of an overview of the methods followed based on the phases of the study and ethical considerations briefly described.

1.11 CONCLUSION

The researcher believes that patient safety measures are required to ensure quality patient care and these are described in later chapters.

CHAPTER 2: RESEARCH PARADIGM AND THEORETICAL FRAMEWORK

2.1 INTRODUCTION

In this chapter, the researcher presents the research paradigm and the theoretical framework that guided this study and its application.

2.2 RESEARCH PARADIGM AND SELECTION OF THE APPLIED METHOD

A research paradigm is a set of common ideas and consensus shared between researchers about how to solve and understand problems (Wang & Zhu, 2016:129-133). It can be distinguished through ontology, epistemology and methodology (Aliyu, Bello, Kasim & Martin, 2014:79-95). Paradigms are linked with assumptions about social and natural reality (Aliyu et al., 2014:79:95).

A researcher must decide which paradigm should be applied in a study, but the choice should depend on the purpose of the study (Easton, 2009:118-128). Furthermore, critical realists do not totally reject empiricist methods such as the use of statistics, but they also believe it is important to examine deeper causal processes at work in the world (Roberts, 2014:1-23).

Guided by the purpose of this study, the critical realism approach was used to investigate adverse events which occurred in HEs and which had resulted in malpractice litigation.

2.3 CRITICAL REALISM

Critical realism is a theory that exists independent of human experiences and awareness (Levers, 2013:1-6). Furthermore, critical realists believe that there is a real world out there in which the language, procedures and explanations that are routinely adopted are viewed (Easton, 2009:118-128). The researcher used the audit instrument that was developed for the purpose of this study to obtain the evidence about the factors that contribute to the occurrence of the adverse events in nursing practice in South Africa. In addition, the audit instrument based on the three components described below enabled adverse events to be defined and identified with their contributory factors. The components are:

- Intransitive dimension
- Critical realism and researcher's assumptions
- Ontology and epistemology

The important understanding of critical realism is that the individual's knowledge is different from the world of existence (Rutter, 2011:7). Also, the world of existence is stratified such that what is experienced in life is not a complete view of the world of understanding (Rutter, 2011:8).

Consequently, the developing properties and different levels of reality which are not properly explained either by modernism or post-modernism approaches are understood (Rutter, 2011:9).

Critical realism and realist ontological perspective are interrelated theories in research (Levers, 2013:1-6). McEvoy and Richard (2003:411-420) believe that 'critical realism is a relatively new philosophical perspective that combines a realist ontology with a relativist epistemology in subscribing to a form of "robust" relativism'.

2.3.1 Intransitive dimension

Bhaskar (1998:3) asserts that reality exists which is not represented by human beings, and it operates in a transitive epistemological dimension and an intransitive ontological dimension. The intransitive dimension was the most important driver that assisted the researcher in deciding which research approach was to be applied in the study (Dobson, 2009:805-810). Bhaskar (1998:4) further emphasises that the intransitive dimension aims to explore the real mechanisms and structures underlying the perceived events. Furthermore, the intransitive dimension assists the researchers to analyse those causal mechanisms in science, which are aimed at discovering perceived ideas (Dobson, 2009:805-810). It is further postulated that the causal mechanisms exist in themselves, regardless of whether humans exist (Bhaskar, 1998:46). Critical realists believe that the social world is which is 'open' provides the opportunity for the researchers to apply a realist methodology of understanding. The open social world which contains numerous causal mechanisms interacting with one another can potentially lead to numerous structural accounts of the same social phenomenon (Roberts, 2014:1-23). The healthcare sectors and factors that contributed to adverse events that may have led to malpractice litigation was the open world which provided the opportunity for the researcher to have identified the need to conduct this study.

Also, the intransitive dimension is divided into the real, the actual and the empirical objects (Hedlund-de Witt, 1998:6). The real refers to the structures, objects that exist, while the actual refers to the activated powers of the real, and the empirical refers to experienced objects (Hedlund-de Witt, 1998:8). Consequently, evidence in research is achieved through investigation, rather than pure observation (Clark, MacIntyre & Cruickshank, 2007:513-539). Roberts (2014:1-23) explains further that, critical realists also believe that the knowledge that people have can be misleading and further research about causal mechanisms in different research contexts must be conducted.

2.3.2 Critical realism and researcher's assumptions

The researcher's assumptions are based on the belief that there are underlying factors which contribute to the occurrence of adverse events which occurred within the HEs of the Gauteng and

Eastern Cape provinces' public health hospitals. Roberts (2014:1-23) explains further that, critical realists also believe that the knowledge that people have can be misleading and further research about causal mechanisms in different research contexts must be conducted. Hence, critical realism was applied in this study to have subjected the researcher's assumptions to social enquiry and avoid many potentially false pathways and avenues (Dobson, 2009:805-810).

Furthermore, the researcher's assumptions regarding the description of the occurrence of incidents which may have led to adverse events were explored (Bergen, Wells & Owen, 2010:442-451). However, if the researcher 's observation is not accurate, it is unlikely that it will lead to a full understanding of any social situation that is completely understood (Easton, 2009:118-128). This theory guided the researcher to choose the research method, design, questions, objectives, and to develop a data collection instrument to obtain an understanding of the factors which contributed to the occurrence of adverse events which lead to malpractice litigation.

Philosophy is important in research as it denotes the researcher's assumptions, values and beliefs about the nature of reality (Hjørland, 2005:5-10). Critical realism offers an opportunity to explore the researchers' assumptions and practices (Gorski, 2009:147-194). In order to explore the causal processes, it is critical to identify the underlying causal powers, or causal mechanisms of an object under investigation and think conceptually about how they operate (Roberts, 2014:1-23). This approach has assisted the researcher in aligning the study research design with actual research practices. The researcher has predicted the outcomes of the research project by exploring the rationale, research questions and objectives of the study (Gorski, 2009:147-194).

Philosophy cannot be proved to be the correct answer in research until subjected to social enquiry (Easton, 2009:118-128). Critical realists believe reality exists so that researchers' assumptions are subjected to social inquiry (Gorski, 2009:147-194). The researcher based her assumptions on the fact that quality health care should be provided at all times so that patients are kept safe, and the desired patient care outcomes are obtained, irrespective of any factors which exist in the HE which could compromise the safety of patients. Consequently, an opportunity for the researcher to provide answers to the question of whether there is a world which exists out there without human consciousness will be provided (Levers, 2013: 1-6). The researcher was able to identify the factors that contribute to adverse events and these factors were classified by using the theoretical framework that guided the study. The results of the comparative analysis that were conducted in phase 2 of the study were applied to develop the guidelines that will contribute to the prevention of malpractice litigation in nursing practice. Within philosophy, critical realism involves shifting from a study of knowledge to a study of existence and within ontology a switch from events to research techniques (Aliyu et al., 2014:79-95).

2.3.3 Ontology and epistemology

Crotty (1998:3- 10) defines ontology as a study of existence and epistemology as a study of knowledge. Guided by critical realism, the researcher aimed at understanding the subjective experience of reality and multiple facts (Levers, 2013:1-6). The study of existence in this study was the existing challenges in nursing practice. The existing challenges included the factors which contributed to the occurrence of adverse events that led to escalating malpractice litigation in the HEs.

Relativist ontology is the belief that reality is a limited subjective experience (Denzin, 2017:307). Hence, the researcher was guided by the critical realism theory, the theoretical framework, the purpose of the study and data collection instrument to analyse this limited subjective experience to produce evidence ultimately.

The epistemological enquiry examines the relationship between the researcher and the literature and creates an opportunity to unearth the existing knowledge and immerse with research evidence (Denzin, 2017:307). Guided by this approach the researcher was able to complete an audit of the nursing process documents in the trial bundles. The nursing process defines nursing patient care in a health institution and includes the assessment of patients; investigations, nursing care plans and nursing management. The principal incident types were determined that were associated with adverse events involving nursing practitioners who were guided by the theoretical framework that is described in paragraph 2.4 below. The objectives as described for this study included to:

- determine the factors that were associated with adverse events involving nursing practitioners.
- identify other members of the healthcare team that were associated with these adverse events. The scope of practice of other healthcare professionals, policies and guidelines guided the researcher.
- determine the severity of the adverse events as defined by the Safety Assessment Code (SAC) (SA Health Risk Management Framework, nd).

The research evidence that was obtained from the above mentioned inquiry was used to develop guidelines that may have contributed to the prevention of malpractice litigation in nursing practice in South Africa. The guidelines were developed guided by the WHO guideline development process as explained in chapter 4 paragraph 4.5.3.1.

Critical realist ontology believes that objects are believed to incorporate realities that are above and beyond the influence of human beings and these essences are discoverable through unbiased observation (Lever, 2013:1-4). Thus, reality exists independently of our knowledge,

even if this knowledge is not accurate (Bergen et al., 2010: 442-451). Hence, the researcher was guided by the purpose of this study to discover the truth about the factors which contributed to the occurrence of adverse events (Lever, 2013:1-4).

The malpractice litigation trial bundles were subjected to an audit process to identify the factors which compromised patient safety.

The audit instrument was used to conduct a retrospective audit analysis to identify and describe the factors that contributed to adverse events in nursing practice South Africa. The new knowledge obtained, generated the development of guidelines, based on the evidence obtained from the three sub-studies of the main study as presented in chapter 6 in this study The guidelines that were developed were grouped into principal types as guided by the theoretical framework.

2.4 THEORETICAL FRAMEWORK

2.4.1 A brief description of a theoretical framework

Theoretical frameworks are developed to explain, anticipate and understand some phenomena (Swanson, 2013: 2). Consequently, a theoretical framework is developed to test the existing knowledge (Swanson, 2013:4), and form the basis from which all knowledge is built for a research study and serves as a structure, a support and provide a grounding base for this study (Grant & Osanloo, 2014:13) and applied to interpret and analyse the collected data (Swanson, 2013:6).

The theoretical framework provided a basis for the researcher's hypotheses and choice of a research method in this study (Grant & Osanloo, 2014:13), and assisted the researcher to articulate her assumptions and created a platform to address the research question designed for this study (Grant & Osanloo 2014:16).

The audit instrument was developed by combining and integrating the processes used in the following:

1. The international classification for patient safety model
2. Generic reference model
3. The Safety Assessment Code (SAC)
4. The nursing process which defines nursing patient care in a health institution (WHO, 2009:1-154) and includes the assessment of patients; investigations carried out, nursing care plans and nursing management.

These models, the severity classification system and nursing process were combined to design the audit instrument used in the auditing of the malpractice litigation trial bundles and to identify the contributory factors of adverse events, which resulted in harm to patients.

2.4.2 Theoretical framework and researcher's assumptions

The researcher believed that the theoretical framework as described by the WHO (2009:1-154) could be applied to identify factors which contribute to adverse events that led to litigation as recorded in the audited trial bundles that formed this study. The theoretical framework guided the researcher to classify and obtain a deeper understanding of the factors that contributed to the adverse events in the public healthcare sector. These factors were classified according to principal types namely: clinical management, behavioural factors, organisational and administrative factors. The severity of the adverse events was classified applying the severity assessment code (SAC) as described in paragraph 2.5. The audit instrument was also based on the nursing process which gave guidance in identifying the healthcare professionals involved in the adverse events.

2.4.3 The international classification for patient safety model

The ICPS defines and groups patient safety concepts, in a manner that they are easily understood and implemented (WHO, 2009:1-154). The purpose of the ICPS for conducting, monitoring and evaluation, analysis and interpretation of patient safety issues (WH0, 2009:1-54). The ICPS is aimed at the development of a quality improvement process designed to identify health risks, solve the problems and improve patient care (WHO, 2009:1-154).

The developed framework consists of the following 10 high-level classes:

- Incident Type
- Patient Outcomes
- Patient Characteristics
- Incident Characteristics
- Contributing Factors/Hazards

- Organisational Outcomes
- Detection
- Mitigating Factors
- Ameliorating Actions and
- Actions Taken to Reduce Risk (WHO, 2009:1-154).

The ICPS is designed to:

- ensure the safekeeping of data in HEs.
- combine, analyse and compare patient safety data across HE departments, examine the roles of system and human factors in patient safety,
- identify potential patient safety issues and develop priorities and safety solutions (WHO, 2009:1-154).

The ICPS' methodology was incorporated into the study audit instrument.

2.4.4 Generic reference model

The Generic Reference Model (GRM) was developed based on a model of complex system failures. Also, the development of this model included the provision of a structured approach to stipulate:

- all the relevant information about an incident and include the overall process of collecting and classifying (Runciman et al., 2006:86)
- the conventional medical record and ancillary information about patients' investigations and procedures
- a system for logging, managing and monitoring progress (Runciman et al., 2006:82).

The GRM underlies the universal patient safety classification developed by Runciman et al. (2006:6) and the International classification for safety (WHO, 2009:1-154).

The models describe the contributing factors which cause an incident resulting in a negative outcome for the individual and consequences for the organisation (WHO, 2009:1-154).

Contributing factors include environmental factors, organisational factors, human capital, subject of incident type and drugs, equipment and documentation. Problems may also include non-application of guidelines, inadequate supervision, communication, junior staff with inadequate training and non-protection ventilation strategy (WHO, 2009:1-154).

Healthcare outcomes for the patient thus may include death, disease, injury and disability, which influence the duration, severity and resource impact (WHO, 2007:9).

An adverse incident may result in unexpected or unwanted effects involving the safety of healthcare users. One incident which is linked to another incident may cause harm (Runciman et al., 2006:83). The best rule is to nominate the incident which led most directly to any harm or potential harm as the principal incident type (WHO, 2007:9).

The generic reference model was incorporated in the study audit instrument.

2.5. THE SAFETY ASSESSMENT CODE (SAC)

2.5.1 Brief description of the safety assessment code (SAC)

Safety assessment code (SAC) is a method used to disclose an incident to the consumer and their carer or support person as soon as possible (South Australia, 2011:2). The SAC scoring method is applied to incidents to assess the consequence or outcome, prevalence and action to be taken.

When applying the SAC scoring method, an incident is identified as an adverse incident. A Panel of Safety Learning Systems is conducted which includes a summary of investigation tests ordered, the impact on consumer outcomes, resource implications and recommendations to prevent a recurrence. The severity of the outcome of an incident as applied by the SAC classification system is rated 1 to 5, namely:

Extreme= 1
Major = 2
Moderate=3
Minor and =4
Insignificant = 5.

The severity of the incident is assessed using a matrix of the actual or potential impact on the patient or organisation and the likelihood of recurrence (SA Health Risk Management Framework, nd). The adverse events in this model are classified as:

2.5.1.1 Extreme rated as 1:

All adverse events that led to death or procedures which resulted in major permanent loss of function whether it is sensory, motor, physiologic or intellectual unrelated to the natural course of the illness or injury and differing from the expected outcome of the management of the patient are described as extreme and rated as 1.

Additional examples are suicide, rape, infant abduction, surgery on the wrong patient, haemolytic transfusion, increase in hospitalisation>125 days and retention of instruments requiring additional surgery. Complete closure of a HE was amongst the adverse events which were rated as 1 (extreme adverse events) (South Australia, 2011:2).

2.5.1.2 Major rated as 2:

Major includes:

- permanent loss of function whether it be sensory, motor, physiologic or intellectual, unrelated to the natural course of the illness and differing from the expected outcome of the management of the patient which may lead to additional surgery, disfigurement
- additional surgery
- an increase in hospitalisation of 25-125 days
- major loss of service to patients such as inability to provide adequate short-term hospitalization, emergency room services and general and specialty surgical services
- the cancellation of booked surgery more than twice.

2.5.1.3 Moderate rate as 3:

A moderate rating includes permanent lessening of bodily functioning whether it be sensory, motor, physiologic, or intellectual. The lessening is unrelated to the natural course of the illness and differs from the expected outcome of the patient, and it includes additional surgery and an increase in hospitalisation from 5-25 days.

2.5.1.4 Minor rated as 4

A minor rating includes patient/s requiring an increased level of care, e.g. a fall resulting in an abrasion. Other examples include:

- medication is given, resulting in allergy not documented and requires transfer to a speciality area for monitoring
- laboratory results unavailable, leading to an unexpected outcome for the patient.

2.5.1.5 Insignificant SAC is also rated as 5. Examples of insignificant ratings include:

The SAC scoring method that is applied to incidents to assess the consequence or outcome, prevalence and action to be taken under this scale is less severe than in minor incidents which are rated 4 according to SAC. This includes patients with no injury and no increased level of stay and may include near misses:

- an incident that requires no increase in the level of care, e.g. a fall sustaining no injuries
- medication omission that resulted in no harm, for example, the wrong medication is drawn up but is noticed before administration
- contaminated clinical waste not cleared away without harm to patients and no loss of service (South Australia, 2011:2).

The Safety assessment code (SAC) (SA Health Risk Management Framework, nd) was used in the study to determine the severity of adverse events identified in the study.

2.6 NURSING ACT NO. 50 OF 1978

The Nursing Act No. 50 of 1978 has not been fully recalled as there are aspects in the nursing profession that are still applicable as described in the regulations below. The trial bundles identified the role of the nurses and their scope of practice with reference to adverse events which led to malpractice litigation. The audit instrument is thus aligned to the applicable legislation.

2.6.1 Regulation 2598 scope of practice as persons who are registered or enrolled as promulgated by the Nursing Act No. 50 of 1978.

The Nursing Act No. 50 of 1978 stipulates the scope of practice of a registered nurse, registered midwife, enrolled nurse and enrolled nursing assistant. In addition, the acts or procedures, which may be performed by a registered nurse, are explained. The acts and procedures that are scientifically based are physical, chemical, psychological, social, educational, and technological applicable to healthcare practice are stipulated. The following duties are encompassed in this regulation:

- A registered nurse diagnoses health needs, draws up care plans, manages the identified problems and refers to the next level when the need arises
- A registered midwife draws up care plans, manages the identified problems and refers mother and child during pregnancy, labour and puerperium to the next level when the need arises. Monitoring of vital signs is also done whilst implementing care plans.

An enrolled midwife identifies health needs, promotes health of the mother and child during normal pregnancy, labour and puerperium

- An enrolled nurse and enrolled nursing assistance shall:

  Identify health needs, promote health of a patient, execute care plans for a patient, monitor vital signs and the observation of reactions to medication and treatment and prevent diseases
- The enrolled nurse and enrolled nursing assistant shall carry out her/his duties under the direct or indirect supervision of a registered nurse, Regulation 2598 Scope of Practice as promulgated by the Nursing Act, 1978 (Act No. 50 of 1978).

2.6.2. Regulations relating to the conditions under which registered midwives and enrolled midwives may practise

Regulations Relating to the “Conditions under which Registered Midwives and Enrolled Midwives may practise to carry on their profession”, R2488 of 1990, as promulgated through the Nursing Act, 1978 (Act No. 50 of 1978), explains that a midwife, medical practitioner or dentist are professionals that are registered in terms of the Act. It further explains the duties and responsibilities of a registered nurse during pregnancy, labour, puerperium and neonatal periods. The regulation further stipulates that the registered midwife shall always make sure that the

equipment and materials that are required in midwifery practice are available and in good working order. Entailed further in this regulation, a responsibility of a registered midwife should keep clear and accurate records of the progress of the pregnancy, labour and the puerperium and of all acts, including emergency acts, which he/she performs in connection with a mother and child. The midwife is also assigned the responsibility with the consent of the mother to call in a medical practitioner in cases of illnesses, abnormalities or complications occurring during pregnancy, labour or the puerperium or in the child.

2.7 NURSING PROCESS

The nursing process forms part of the theoretical framework. The trial bundles showed that the nursing documentation was based on the nursing process. Thus the audit instrument was also based on the nursing process as guided by the trial bundles. A brief discussion about the nursing process is described in this chapter and more detail in chapter 3.

The nursing process is a systemic technique that was designed by Ida Jean Orlando in the year 1958, and Hall originated the term in 1955 (Hala & Bayoumy, 2014:3).

Aseratie, Murugan and Molla (2014: 1-8) define the nursing process as a five-step systematic problem-solving approach used to identify, prevent and manage the health problems. The five steps of the nursing process are:

- assessment
- diagnosis
- planning
- implementation
- evaluation

The audit instrument is set out in Annexure 1: Audit instrument.

2.8 SUMMARY

In this chapter, the researcher presented the research paradigm and theoretical framework that guided this study and its application.

2.9 CONCLUSION

The researcher concludes that the 'real' world in this study could not be observed and it existed independently from human perceptions, theories, and constructions. Guided by this paradigm and the theoretical framework the researcher was able to classify and get a deeper understanding of the factors that contributed to adverse events contributing to malpractice litigation in nursing practice in the HEs that resulted in malpractice litigation in nursing practice in South Africa.

CHAPTER 3: LITERATURE REVIEW

3.1 INTRODUCTION

In this chapter, a literature review related to the purpose and objectives of this study is discussed to provide a detailed understanding of the factors that contribute to adverse events resulting in medical malpractice litigation cases in nursing practice.

Patients have high expectations of healthcare professionals, and expectations include safe quality care (Hwang, Wu, Cheng &Yen, 2018:1-7). The Universal Declaration of Human Rights has been a good guide to ensure that the belief of human dignity is incorporated in international laws and policies. The declaration provides proper guidance for acceptable standards of care (WHO, 2019:1). The National Patients' Rights Charter (National Department of Health, 2008) was developed to ensure that the rights that are to be enjoyed by every patient who accesses a HE in South Africa are clearly stated in Patients 'Rights Charter. Also, the Department of Health introduced the National Core Standards to guide the healthcare delivery system with regards to the expected standards of care in the HE at all levels of care.

The National Core Standards (NCS) are based on seven domains (risk areas) that aim at ensuring safe quality care to patients and guide healthcare sector safe quality service delivery and include:

1. Patient Rights
2. Patient Safety
3. Clinical Support and services
4. Public Health
5. Leadership and corporate governance
6. Operational management
7. Facility and infrastructure

(National Department of Health, 2011: 2).

The nurses should strive to deliver high quality of care, irrespective of the challenges they are faced with in their practice. Mitchell (2013: 513-518) substantiates that nursing is often viewed as providing the safety which includes beneficence, i.e. avoiding harm to patients.

In South Africa, the Health Amendment Act, 2013 (Act No 12 of 2013), was introduced to establish the Office of Health Standards Compliance (OHSC) to ensure that HEs comply with the national norms and standards. However, inspection statistics released for 2014-2015 for the

Parliamentary Portfolio Committee show that 40% of the HEs are critically non-compliant, and 28% are non-compliant (OHSC, 2016).

Factors influencing patient safety and quality in general, within a complex healthcare environment are challenging (Mitchell, 2013:513-518). These include the burden of disease, budget constraints, managerial profit targets, employing incompetent staff, shortage of nurses, changing technology and complex ethical decision making. Also, patients are subjected to poor infrastructure; lack of staff, equipment and supplies, and incompetent staff. These deficits in HE may cause adverse events (Stellenberg & Dorse, 2014:1). Thus, it becomes the responsibility of the organisation to provide quality and safe patient care.

The aetiology of adverse events is multifactorial and not always be attributable to clinical negligence. According to Dekker (2012:371-385) the emphasis on human error is an old view when organisations blamed the staff member for incompetence, in contrast to the new view that human error is an organisational problem.

Unfortunately, medical errors occur frequently and may lead to adverse events such as death (Matharoo, Haycock, Sevdalis & Thomas-Gibson, 2016:83-89). Substandard care in nursing practice may lead to medical errors which may result in malpractice litigation. Malpractice litigation sometimes leads to medical pay-outs (Hwang et al., 2018:1-7).

In light of the above, the researcher discusses factors contributing to the origin or development of incidents that can lead to adverse events and malpractice litigation in nursing practice.

3.2 MEDICAL MALPRACTICES

Medical malpractice and medical negligence are used interchangeably in the HE. Malpractice is explained as a healthcare practitioner ‘s failure to provide the expected care and skills as stipulated either in legislation, policies of the governing body and employer (Mosime, Reddy and Karodia, 2016:149-190). Brock, Nicholson and Hooker (2017:613) further define malpractice as a deliberate failure to provide care or act of incompetence by a professional. Professional medical negligence often results in litigation (Moore & Slabbert, 2013:1-36). Also, negligence is the failure of the defendant to foresee the possibility of harm (Moore & Slabbert, 2013:1-36). Mosime et al. (2016:149-190) further substantiate that medical practitioners may purposely deviate from providing medical care. Brock et al., (2017:613) emphasise that medical negligence can cause significant and permanent injuries.

3.2.1 International perspective

According to Hambali and Khodapanahande (2014:76-83), a noticeably increased rate on medical malpractice can attract publicity through the media, researchers and government annual

reports. They further indicate that increased rate of medical practice claims is associated with a lack of properly managed justice systems (Hambali & Khodapanahande, 2014:76-83). Hwang et al. (2018:1-7) explain that twenty-one claims were dismissed in Taiwan because of improper legal processes.

3.2.1.1 The effects of malpractice litigation on healthcare professionals

Malpractices may lead to lawsuits, healthcare professional burnout and job dissatisfaction (Hall, Johnson, Watt, Tsipa & O'Connor, 2016:1). Hall et al. (2016:2) further reported that 16.6% of inpatient malpractice cases occurred in Australian Hospitals and 3.7% in America, and these resulted in severe adverse events.

A comparative study amongst the physicians, nurses and physician assistants conducted in America revealed that physicians had higher reported malpractice reports than adverse events (63.0% vs 37.0%). This study also revealed that nurse practitioners had fewer malpractice reports (28.1%) than adverse events (71.9%) (Brock et al., 2017: 619). A retrospective study conducted in Taiwan to review Taiwanese civil court medical malpractice verdicts from 2002 to 2013 identified that obstetrics and surgery were the riskiest specialities that lead to malpractice litigation in Taiwan. Obstetrics accounted for 10.7 %, and surgery accounted for 39.4%.

3.2.1.2 The effects of malpractice litigation on budget

An estimated sum of £1.3 billion was paid out for National Health Laboratories (NHL) medical errors, and £2 billion paid additional hospital errors due to malpractice litigation (Hall et al., 2016:2). A study conducted by Matharoo et al. (2016:83-89) in the United Kingdom revealed that 61% of malpractices were found in diagnostic cases and 61% within the therapeutic cases. Plaintiffs (67.9 %) with known litigation outcomes received monetary compensation for death or disability, emotional harm, funeral expenses and the living expenses of dependents in China (Hwang et al.,2018:1-7).

3.2.1.3 Factors that contribute to adverse events

Uramatsu, Fujisawa, Mizuno, Souma, Komatsubara and Miki (2017:7) explain that many factors contributing to adverse events arise from a chain of failures. Thus, the clinicians, managers and many factors in HE may contribute to the occurrence of adverse events in HE (Uramatsu et al., 2017:7). Runciman et al. (2006:82-90) and the WHO (2009:7) further explain that negative outcomes are the worst experiences in the health sector, which may cause harm or loss to the patient and the organisation. Matharoo et al. (2016:83-89) conducted a study in the United Kingdom on patient safety incidents in gastrointestinal endoscopy and the study revealed that adverse events occurred due to poor oxygen monitoring, poor time management, poor documentation and reporting, poor training, lack of resources, drug errors and improper ways of

obtaining consent from patients. Hanlon et al. (2015:2) state that substandard care may lead to adverse events and malpractice litigation.

A study conducted in China to assess the characteristics and incidence of medical litigation revealed that 89.6% of cases occurred due to injury, a lack of consent (25.1%), misdiagnosis (21.7%), delay in treatment (21.2%) and alteration or forgery of medical records (18.0%) (Hwang et al., 2018:1-7). Substantiated further a study conducted in England and Wales, revealed that 75% of all reports included during patient discharge were incomplete (Hibbert, Hallahan, Muething, Hooper, Wiles, Jaffe, White, Wheaton, Runciman, Dalton, Williams & Braithwaite, 2015:1-14).

3.2.2 National perspective

3.2.2.1 The effect of malpractice litigation on budget

The increased rate of malpractice litigation is amongst the challenges that affect healthcare service delivery in both the private and public sector of South Africa. Health Minister Dr Motsoaledi, (March 2019) announced that South Africa faces litigation in public healthcare of R90 billion. According to The Acting Chief Litigation Officer of the Department of Justice and Constitutional Development (DOJCD), the principal amounts paid out for litigation on behalf of the National Department of Health by the offices of the State Attorney amounted to a sum of R 498 964 916.72 during 2013/2014. Dr Motsoaledi and Ms Mahlangu confirmed, there were 2000 pending court cases against the Gauteng Department of Health and unbudgeted quantum claims amounting to approximately R3.5 billion (Dhai, 2015: 2).

3.2.2.2 The remedial action to address the increased rate of malpractice litigation

Unfortunately, the South African Government has no existing law that is in place to address claims in medical negligence except common law (South African Law Reform Commission, 2017:1). Furthermore, the legal fraternity decided to make the public aware of their rights. Consequently, this has become one of the contributory factors to the increase in malpractice litigation (Mosime et al., 2016:149-190). Child (2015:1) indicated that Health Minister Dr Aaron Motsoaledi tried to avoid the bankruptcy of the National Department of Health by announcing an investigation into the cause of the increased malpractice litigation. The purpose of the investigation was to ensure that recommendations and remedial actions about preventing the increased malpractices are in place (Child, 2014:1). Substantiated further, South African Law Reform Commission (2017:36) requested the public to provide input on issues that may assist in the reduction of the number of increased malpractice litigation issues such as proper record keeping, improved communication amongst healthcare professionals and reviewed consent forms.

Moore and Slabbert (2013:1-36) indicate that measures such as collegial peer review, quality communication amongst staff members and continuing staff development may assist at limiting adverse events that may lead to an increased rate of malpractice litigation.

3.2.2.3 Effects of malpractice litigation on service delivery

Judge Neels Claasen (2016:6) explains that increased medical claims destroy healthcare delivery systems and result in some healthcare professionals leaving the medical profession, some professionals doing unnecessary diagnostic tests to increase the medical costs and often cause further grounds for claims against the institution.

Mosime et al. (2016:149-190) conducted a study in Eastern Cape Province of South Africa to investigate the impact of medical malpractice litigation on healthcare delivery. The study revealed many factors contributing to increased malpractice litigation in South Africa. The factors included: 78.5% skill shortage, 71.0% inexperienced healthcare professionals, healthcare professionals practising above their scope of practice.

3.2.2.4 Factors that contribute to malpractice litigation

Several factors may lead to increased malpractice litigation, and these include poor healthcare service delivery and advertising by lawyers (Dhai, 2015:2). As illustrated in a study conducted in the Eastern Cape Province in 2014 about near-miss maternal morbidity in South Africa, it was revealed that 13 hospitals had nine (9) blood banks, eight (8) multidisciplinary ICUs and nine (9) obstetric high-care areas, eleven hospitals had one specialist obstetrician and gynaecologist available in case of emergencies (Maswime & Buchmann, 2017:1005-1009).

3.3 ADVERSE EVENTS

Saranto, Kinnunen, Kivekas, Lappalainen, Liljam and Rajalahti (2014:629-649) define adverse events as a simple quantitative method of recognising unsafe patient care. Adverse events are also explained as preventable incidents that occurs because healthcare providers did not take adequate measures during healthcare delivery (Schildmeijer, Unbeck, Ekstedt, Lindblad & Nilsson, 2018:3). A decline in patient safety measures is a contributory factor to the occurrence of adverse events that may lead to malpractice litigation (Seige, 2013:2).

3.3.1 Effects of adverse events on patients

Unsafe patient care may result in an increased rate of adverse events that may result in high mortality and morbidity rates (Slawomirski, Auraaen & Klazinga, 2017:27). Substantiated further Kang, Kim and Lee (2014: 273–280) believe that the outcome of the adverse events is the indicators of substandard care rendered to patients. The outcome of adverse events may result

in injuries, death, disability or prolonged hospital stays and use of additional resources (Kang et al., 2014: 273–280).

3.3.2 Effects of adverse events on budget

Adverse events are resulting in an economic burden that varies from 1.3% to 32% in public HE (Slawomirski et al., 2017: 27). South Africa faces litigation in public healthcare of R90 billion (Minister Dr Motsoaledi, March 2019). Patient harm remains high, leading to 15% of the HE expenditure that is incurred for the payment of adverse events (Slawomirski et al., 2017: 5). This was confirmed by the acting Chief Litigation Officer of the Department of Justice and Constitutional Development (DOJCD) in her presentation on the problems and costs related to the high incidence of medico-legal claims against the state at the March 2015 Medico-legal Summit. She indicated that the principal amounts paid out for litigation on behalf of the Department of Health by the offices of the State Attorney amounted to R40 923 535 000 between the year 2015- 2016 (African law reform commission 2017:17).

It is reported that in the public sector of developing countries, 15% of expenditure is because of adverse events (Slawomirski et al., 2017:27). Additionally, an approximation of hundreds to trillions of US dollars are utilised on adverse events (Slawomirski et al., 2017:18).

In the United States, approximately two million healthcare associated infections occur annually which accounts for an estimated 90,000 deaths and are costing more than $4.5 billion in hospital health care (Hanlon et al., 2015:17).

The increase in payments for medico-legal claims means that money has to be diverted away from the delivery of health care services, (African law reform commission 2017:17).

3.3.3 International perspective

Zegers, Hesselink, Geense, Vincent and Wollersheim (2016:1) explain that there is a 10% prevalence of patient harm and death which results from adverse events worldwide.

3.3.3.1 Adverse events due to resources

A study was conducted over one year in America to monitor ICU physicians and nurses. The study revealed that 390 incidents that were identified were due to equipment, medications, technical and administrative procedures of which human error was the main cause of adverse events (Duarte, Stipp, Silva & Oliveira, 2015:136-154). The adverse events varied depending on the patient's length of hospital stay (Duarte et al., 2015:136-154).

3.3.3.2 Adverse events due to avoidable factors

Adverse events may occur due to avoidable factors such as discharging patients prematurely in some Health Establishments. A retrospective study conducted in Sweden to explore the origin, incidence, types and preventability of adverse events that occur in patients receiving home healthcare revealed that 80.8 % of adverse events were preventable (Schildmeijer et al., 2018:3).

3.3.3.3 Adverse events due to system failure

Uramatsu et al. (2017:7) explain that many factors are contributing to adverse events arising from a chain of failures. Thus, the clinicians, managers and many other factors in the HE may contribute to the occurrence of adverse events (Uramatsu et al., 2017:7). Shortage of resources poses a challenge for a HE manager as it may lead to substandard care that may lead to adverse events (Asiri, Rohrer, Al-Surimi, Da'ar & Ahme, 2016:3). Asiri et al. (2016:3) further explain that management styles, such as autocratic and weak leadership styles may have a negative effect on nursing practice. Weak leadership includes poor planning, poor decision making and autocracy. In the USA 13.5% or 1:7 of one million discharged Medicare beneficiaries had an adverse event of which 1.5% (15 000) died within one single month, due to an adverse event (United States of America Department of Health and Human Services, 2010). Furthermore, medical error is the third cause of death in the United States of America. During the period 2000-2002, 575 000 deaths occurred, i.e. 195 000 per year, while in 2008, 180 000 deaths occurred due to health hazards (Makary & Daniel, 2016:1). In the United States, about two million healthcare-associated infections occur each year which account for an estimated 90 000 deaths and are costing more than $4.5 billion in hospital health care (Hanlon, Sheedy, Kniffin & Rosenthal, 2015:17).

Adverse events occur when the required nursing care is not rendered (Carthon, Lasater, Sloane & Kutney-Lee, 2015: 255-63), as found in a study conducted in California, New Jersey and Pennsylvania from 2005 to 2006. The readmission of 160 930 patients with heart failure in 419 acute-care hospitals was explored. The results of this study revealed that the most frequently missed nursing care activities included the following: talking to and comforting patients (42.0%), developing and updating care plans (35.8%) and educating patients and families (31.5%) (Carthon et al., 2015:255-63). An Irish study that was conducted to assess the frequency and nature of adverse events in Irish hospitals, revealed that 70% of the adverse events that occurred were surgically related, 50% therapeutic, 30% medication-related, 20% fracture related, 10% fluid-related and 10% pregnancy-related (Rafter, Hickey, Conroy, Condell, O'Connor, Vaughan, Walsh & Williams, 2016:1-12).

3.4 LEGISLATION

The South African Constitution (Act 106 of 1996) states in two sections the right to healthcare, namely:

- Access to healthcare services including emergency services and reproductive health
- Basic health care for children

Furthermore, in paragraph 3.4.1.5, the National Health Amendment Act No. 12 of 2013 state the measures that are supposed to be in place for effective service delivery.

Nursing is an art, which includes commitment, knowledge, efficiency and accountability (McLeod-Sordjan, 2014:472). Mitchell (2013: 513-518.) explains that nurses have a responsibility to ensure health promotion, provide quality care and prevention of illness. Nurses provide safe patient care that is a key factor in healthcare outcomes (Jones, 2016:7). Therefore, the public expects quality care from the nurses (McLeod-Sordian, 2014:474-480). However, professional obligation to provide safe patient care does not guarantee the outcome of care provided to the public (Duarte et al, 2015:136-154).

Hibbert et al. (2015:1-8) indicate that the involvement of nurses can lead to a commitment to their employer and nursing profession.

3.4.1 National nursing perspective

One of the responsibilities of the South African Nursing Council (SANC) (Nursing Act No. 33 of 2005) is to ensure that nurse professionals conduct themselves in a professional manner and maintain practice standards and policies,

3.4.1.1 Nursing Act No.33 of 2005

SANC is entrusted with the responsibility of serving and protecting the interests of the public SANC has to ensure that it investigates any complaints lodged by the public concerning misconduct of the healthcare professional. Thus, the necessary disciplinary actions are taken against the alleged professional. The scope of practice of a registered nurse entails the acts or procedures, which may be performed by scientifically based physical, chemical, psychological, social, educational and technological means applicable to health care practice: This act further explains the following categories in the nursing profession:

- Professional nurse: Is a qualified, independent, competent, responsible practitioner that is able to practise comprehensively and accountably.
- A midwife: Is a qualified and competent practitioner that is able to function in midwifery independently, practise comprehensively and can assume her duties responsibly and accountably

- An enrolled nursing assistant or a registered midwife: Is a practitioner who practises the skills under the direct and indirect supervision of a registered nurse or registered midwife

3.4.1.1.1 Regulation 767 of 1 October 2014: Acts and Omissions

Regulation 767 Acts and Omissions as promulgated through the Nursing Act, 2005 (Act No. 33 of 2005), states the conditions under which a nurse professional can be disciplined by the SANC when misconduct has been committed. The regulations further explain that the acts include wilful or negligent actions to diagnose, treat, care, prescribe, collaborate, refer, coordinate, patient advocacy as permitted by the scope of practice.

3.4.1.2 National Health Amendment Act No. 12 of 2013

Amendment of chapter 10, section 79 of the National Health Act 61 of 2003, states that HEs should comply with quality standards and requirements as required by the Minister of Health. This act further states that the Office of Standards Compliance and the Inspectorate for Health Establishments must monitor and enforce compliance with the quality requirements and standards contemplated.

To ensure that the above-mentioned responsibility is fulfilled the Health Act 61 of 2003 was amended and the National Health Amendment Act No. 12 of 2013 was introduced, which established the Office of Health Standards Compliance.

The objectives of this Office are to protect and promote the health and safety of users of health services by:

- Enforcing compliance to set norms and standards of which monitoring, investigation and disposal of complaints that relate to noncompliance are attended to. (National Health Amendment Act No. 12 of 2013).

3.4.2 International perspective

There must be continuous improvement of care so that there are proper identification and prevention of the factors that may result in adverse events in the HEs (World Health Organization (WHO), 2013:29). Professional nurses are accountable to execute their independent functions within their scope of practice (Geyer, 2016:51-52). Geyer (2016:51-52) explains that the scope of practise is dynamic so that it caters for new developments in nursing, midwifery and healthcare at large. It is postulated that people in need of care are assisted to cope with illness and treatment will be rendered accordingly (California Legislative Information, 2013: 2725 – 2742). Thus, nurses in each country have to be licenced by a governing body or some guiding laws and regulations so that they are permitted to execute nursing care activities (Geyer, 2016:51-52).

The International Council of Nurses (ICN) of which South Africa is a member serves as a body that gives guidance to adherence of ethical standards. The main objective of the (ICN) is to ensure respectful care, quality care and professionalism in the nursing profession (International Council of Nurses, 2012:2).

3.4.2.1 Nurses associations

In countries such as Canada the nursing association, namely, The Canadian Nurses Association (CAN) regulates nursing education and practice. This association also took the initiative of ensuring the quality of care by setting standards that guide the nursing profession (O'Malley, 2014:1). In America, the American Nurses Association (ANA) ensures implementation of the nursing standards, ensure safe and ethical work environment and ensure wellness of nurses (O'Malley, 2014:2). In Kenya, the National Nurses Association of Kenya is a professional body that is responsible for the welfare of nurses (Wagoro & Rakuom, 2015:31-39).

3.5 PATIENTS' RIGHTS

As described in paragraph 3.1, the human rights to dignity, safety and equality have been recognised by The Universal Declaration of Human Rights since 1948 (WHO, 2019:1). Thus, it becomes a responsibility of each state to ensure all citizens have access to quality patient care (WHO, 2019:2). The National Department of Health has a responsibility of ensuring that there are safe and quality health services that are delivered in HEs. The National Department of Health (2008) took the initiative of ensuring that the citizens of South Africa enjoy the Constitutional rights of the country by introducing the Patients' Rights Charter. The Charter is a document that empowers health users about their rights and responsibilities as patients.

3.5.1 Patients' rights charter

The National Patients' Rights Charter (National Department of Health, 2008), states clearly the rights that are to be enjoyed by every patient who accesses a HE in South Africa.

The rights are:

3.5.1.1 Healthy and safe environment

This right stipulates that human beings have a right to a healthy and safe environment that will ensure their physical and mental health or well-being. Adequate water supply, sanitation and waste disposal are listed as requirements that need to be in place to ensure a safe and healthy environment. In addition, care should be taken to avoid environmental danger, such as pollution, ecological degradation or infection.

3.5.1.2 Participation in decision-making

Every citizen has a right to informed decisions on matters affecting their health. This right puts a responsibility on healthcare workers to ensure that all service users are provided with information so that the decisions that they take are based on adequate information that they have received.

3.5.1.3 Access to healthcare

This right stipulates that all citizens have the right to access healthcare services. Everyone has a right to:

- receive timely emergency care at any healthcare facility that is operating irrespective of the ability to pay
- have knowledge about the available services on treatment and rehabilitation thereof
- be provided with special needs in case of new-born infants, children, pregnant women, the aged, disabled persons, patients in pain, persons living with HIV or AIDS patients
- be provided with counselling without discrimination, coercion or violence on matters such as reproductive health, cancer or HIV/AIDS
- Be provided with palliative care that is affordable and effective in cases of incurable or terminal illness

3.5.1.4 Knowledge of one's health insurance/medical aid scheme

This right stipulates that the medical or health insurance member should be well informed about the scheme and challenge the decision of the scheme where necessary.

3.5.1.5 Choice of health services

Everyone has a right to choose a healthcare provider and HE, and the choice shall not be contrary to the ethical standards applicable to such a healthcare provider or facility.

3.5.1.6 Treated by a named healthcare provider

Every healthcare provider should be identified so that the healthcare customer knows who is attending to him/ her.

3.5.1.7 Confidentiality and privacy

The healthcare user should be the one who gives consent for the disclosure of the information concerning one's health and treatment, except when requested by the law or court order.

3.5.1.8 Informed consent

Everyone has a right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and risks associated with and the costs involved.

3.5.1.9 Refusal of treatment

A HE customer has a right to refuse treatment, and such refusal shall be verbal or in writing, provided that such refusal does not endanger the health of others.

3.5.1.10 A second opinion

Everyone has the right to request a second opinion to a health provider of one's choice.

3.5.1.11 Continuity of care

Everyone has a right not to be abandoned by a healthcare professional who or a health facility which initially took responsibility for one's health without appropriate referral or hand-over.

3.5.1.12 Complaints about health services

Everyone has the right to complain about healthcare services, to have such complaints investigated and to receive a full response on such investigation.

3.6 NURSING PROCESS

Aseratie, Murugan and Molla (2014: 1-8) define the nursing process as a five-step systematic problem-solving approach used to identify, prevent and manage the health problems. The nursing process is briefly described in paragraph 2.7 chapter 2. The five steps of the nursing process are:

- assessment
- diagnosis
- planning
- implementation
- evaluation

The systematic steps that are used in a nursing process document in Kenya are assessment, diagnosis, outcome identification, planning, interventions, implementation and evaluation. It was designed to be a tool that is used to promote evidence-based practice, address and identify individual patient problems (Wagoro & Rakuom, 2015:31-39).

It is substantiated that nurses do have knowledge about the implementation of the nursing process but cannot implement it properly. The challenges that the nurses are faced within nursing practice result in improper implementation of the nursing process (Aseratie et al., 2014: 1-8). A study conducted to assess factors affecting implementation of the nursing process among nurses in selected governmental hospitals in 2011 at Addis Ababa, Ethiopia revealed that 52.1% nurses implemented nursing process while 47.9% were not implementing the nursing process (Aseratie et al., 2014:1-8).

3.6.1 Assessment

Assessment is the initial stage of the nursing process during which patients' problems are identified, prioritised, and nursing diagnosis is formulated (Bradbury-Jones & Clark, 2016:1-4). Leslie (2018,2) highlighted the following areas that the nursing assessment should address activity or rest, circulation, ego integrity, elimination, food or fluid, hygiene, neurosensory status, pain or discomfort, respiration, safety, sexuality, social interactions, and teaching or learning needs. Haapoja (2014:5-11) substantiated that the nurse needs to assess and interpret the data collected. Haapoja (2014:5-11) defines the assessment stage as a stage where a nurse collects both subjective and objective data from the patient. Subjective data involves verbal statements from the patient and objective data is measurable data such as vital signs, intake and output, and height and weight (Van Hecker, Beeckman, Grypdonck, Meuleneire and Hermie, 2013:381-387). This phase assists nurses to recognise the prevalence of diseases while they gather more knowledge about the diseases (Bradbury-Jones et al., 2016:1-4).

3.6.2 Nursing diagnosis

A nursing diagnosis is the second stage that needs critical thinking where a nurse analyses all the data collected from the assessment stage and formulate a diagnostic statement (Haapoja, 2014:7). Unfortunately, at times when outpatient care is fragmented timeous assessment and diagnosis may be at risk (Hart, Spiva, Baio, Huff, Whitfield, Law, Wells, Mendoza, 2015:2769-2778). Alternatively, nurses should systematically review the patient‘s problem areas (Makala, 2015:1-5). This stage is encompassing Maslow's Hierarchy of Needs; it helps to prioritise and plan care based on patient-centered outcomes (Haapoja, 2014:5-11).

It is a responsibility of a nurse to establish a correct diagnosis so that timeous therapeutic care plans are formulated; errors and adverse events are eliminated (Almeida & Pimentel, 2016:128-135).

3.6.3 Planning

Amakali (2015:1-5) believes that planning is goal-driven, objectives, nursing interventions and outcomes of care are set during this stage. This stage depends on the assessment and nursing diagnosis, of which the nurse sets measurable, achievable short-term and long-term goals of care (Patiraki, Katsaragakis, Dreliozi & Prezerakos, 2017:88). Assessment data, diagnosis and goals are written in the patient's care plan so that the health professionals caring for the patient have access to it (Patiraki et al., 2017: 88).

3.6.4 Implementation

In this stage, the nurse carries out the nursing interventions that are highlighted in the planning stage. Implementation is the step which involves the actual carrying out of nursing interventions

outlined in the plan of care. The nurse implements care plans to ensure continuity of care and in preparation for discharge (Patiraki et al., 2017:88).

Geyer (2016:51-52) stipulates that nursing care activities should be holistic of which history taking, screening for diseases, immunisations, home visits, patient audits, community developments, community health education, problem-solving, promoting cultural safety and respect, professional development and continuous communication with stakeholders should be practised. It is a legal requirement that all healthcare professionals comply with these prescriptions (Geyer, 2016:51-52).

3.6.5 Evaluation

Evaluation is a stage where the nurse continuously evaluates the effectiveness of the nursing care activities documented in the implementation and planning stages. The nurse then modifies the care plan as needed (Patiraki et al., 2017:88). The nursing process is a continuous process that is reviewed and updated to ensure patient safety, quality care and comprehensive healthcare (Haapoja, 2014:5-11). Haapoja (2014:6) further explains that if the patient‘s condition does not improve the scientific nursing process is recommenced from stage 1 to stage 5, i.e. the patient is reassessed, nursing diagnoses formulated based on the assessment and adjusted care plans are implemented.

3.7 CLINICAL MANAGEMENT

Clinical management includes all the processes which occur during patient care in a HE. These processes include continuous monitoring, diagnosis, planning, intervention and patient advocacy, which are critical to all hospitalised patients (Alper, O’Malley & Greenwald, 2017:3). It is further explained that nursing interventions, patient rehabilitation, prevention of disease, patient education, counselling; discharge planning, coordination of care; assistance with ambulation and medication administration are imperatives that are important during clinical management (Heslop & Lu, 2014:2469-2473). Dyess, Sherman, Pratt and Chiang-Hanisko (2017:309-310) believe that competency of a professional should be based on set standards.

3.7.1 Clinical competence

Numminen, Leino-Kilpi, Isoaho and Meretoja (2015:845-859) define clinical competence as a professional nurse’s ability to perform her duties and integrate attributes such as knowledge, skills, attitudes and values in nursing practice. Melnyk, Gallagher-Ford, Long and Fineout-Overholt (2014:5-15) further explains that nurse practitioners’ attributes such as knowledge, psychomotor skills and affective skills are required to maximise patient care.

The HE has a responsibility to ensure that competency skills, knowledge, interpersonal relations and attitudes are reinforced all the time (Hwang, 2015:236). In addition, a standardised on-going process of in-service training on competency skills can be of assistance for high-quality patient care (Melnyk et al., 2014:5-15). Hwang (2015:237) believes that valid and reliable tools can be useful to identify nurses' strengths and weaknesses.

3.7.2 Patient medication

The nurse is tasked with a responsibility to administer each medication as per doctor's prescription. It is therefore expected that the nurse has knowledge about the therapeutic effects and side effects of each drug that she is administering to a patient (Amakali, 2015:1-5).

Administering medication and documenting what was given remains vital during clinical management, as poor documentation may lead to a medication error (Saranto et al., 2014: 629–647). It is indicated that phone calls, nurses talking to one another while giving medication to patients, shortage of resources and constant interruption during the administration of medication are contributing to medical errors (Flynn, Evanish, Fernald, Hutchinson & Lefaiver, 2016:19-36). Interruption during medication rounds can lead to wrong medication given via the wrong route (Flynn et al., 2016:19-36).

3.7.3 Documentation

Documentation should be a continuous nursing activity, from patient admission until discharge. Kerr, Klim, Kelly and McCann (2016:90) explained that documentation is a written communication that assists in transferring information and responsibility during shift handover, discharge of a patient or transfer. It assists the health professionals to make decisions that are guided by the available information in patients' records (Elliott, Page & Worrall-Carter, 2012:22-28). Documentation is the best tool in research as it is a source of knowledge (Haapoja, 2014:7). Haapoja (2014:8) further explains that documentation assists in analysing the relationship between the nursing interventions and outcomes.

Legible and clear documentation, where professionally accepted official language is used may lead to quality patient care (Haapoja, 2014:7).

3.7.4 Discharge plan

Discharge planning should be practised and be a standardised norm in each HE. The main aim of discharge planning is to reduce hospital length of stay, ensure continuity of care even post-discharge, coordination of services and prevention of readmission (Gonçalves-Bradley, Lannin, Clemson, Cameron & Shepperd, 2016:2). Patient education should be given to patients before discharge, although it cannot be guaranteed that it can prevent readmission. The family members

should be included in this education for support. The information that is given to patients during discharge includes: diet, self-administration of medication, lifestyle modification, side effects and effects of drugs, change in risky lifestyles such as smoking and alcohol abuse and importance of follow up visits (Amakali, 2015: 1-5).

Hibbert et al. (2015:1-8) emphasise that the discharge planning should be filled in as it is a communication tool between the primary and tertiary HEs.

The following factors need to be checked before discharge:

- Activity level, functional and cognitive status
- Home environment including the availability of family support
- Availability of transportation services to home and for follow-up visits and the ability to obtain medications and services and
- Availability of community services that will assist the patient with ongoing care (Alper et al., 2017:3).

3.8 HUMAN BEHAVIOUR PROBLEMS

Openness, transparency, reflection and learning, honesty, respect, teamwork, hierarchies, beliefs, values and ideologies are the critical aspects that are supposed to be in place in HE professional behaviours (Slawomirski et al., 2017:28). Factors such as staff shortage, work overload, compulsory overtime, and conflicts may affect the behaviours of nursing personnel negatively (Farahani, Oskouie, Ghaffari, 2016:1-10). It is explained further that, when an error has occurred during patient care, nurses prefer a non-punitive response from their managers (Quillivan, Burlison, Browne, Scott, James & Hoffman, 2016:383).

3.8.1 Human error

Measures are taken to ensure proper patient safety, but human errors remain common in a HE (Duarte et al., 2015:136-154). These include planned activities that fail to produce their intended outcome in the process of healthcare delivery (Reason, 1990:9). Activities may include trained and highly dedicated professionals who make errors due to the complexity of a HE (Uramatsu et al., 2017:7). Additionally, the staff involved in these errors may develop a lack of understanding of how the error occurred (Duarte et al., 2015:136-154). Sokol-Hessner, Folcarelli and Sands (2015:1) substantiate that human errors that occur in the HE is sometimes unnecessary that could be prevented. Thus, patient outcomes, either positive or negative, are the consequences of behaviours (Slawomirski et al., 2017: 22). Consequently, emotional harm may damage a nurse-patient relationship with healthcare professionals (Sokol-Hessner et al., 2015:1).

3.8.1.1 Human error and mitigating human errors

Reasons (1990:10) refers to mitigating human errors in his "Swiss cheese" model of human error trapping as four levels each level affecting another level. Reasons (1990:10) further substantiate those four levels as resembling Swiss cheese, of which the first level resembles the unsafe practices that consequently lead to adverse events.

3.8.1.2 Human error and management

It is a responsibility of the HE managers to explore the reasons for the occurrence of human error by checking if the employee intended to cause harm (National Department of Health, 2016:17). Nurses are sometimes faced with challenges that can lead to poor practice, medical errors and stress (Moore, Everl & Bauer, 2016:2). Massey, Chaboyer and Anderson (2016: 6-23) conducted a study and identified that feelings such as anxiety and fear may arise when a nurse lacks guidance in delivering healthcare.

Consequently, the nurses may feel anxious, demotivated and blamed for the error that has occurred (Massey et al., 2016:6-23). Sokol-Hessner et al. (2015:4) emphasise that when healthcare workers' psychological state is compromised patient safety can be negatively affected. A study conducted in Japan revealed that healthcare providers with depression were bound to make errors (Niven & Ciborowska, 2015:207-215).

3.8.1.3 Staff members and human errors

It is not always the case that the patient suffers emotional harm because respect was not given to the patient, but the disease itself may be contributory (Sokol-Hessne et al., 2015:4).

The results of a study conducted in the Regional Council of Medicine in the State of Sergipe, 1 January 2004 and 31 December 2013 revealed that 29 cases due to medical errors resulted in 48% of staff being punished and 52% were penalised (Almeida & Pimentel, 2016:128-35).

Sleep deprivation of staff may result in staff negative feelings, which may escalate the problems that occur in nursing practice (Massey et al., 2016:6-23). A study was conducted to investigate the link between sleep deprivation and errors among 289 female nurses working as night staff in a hospital. The results of this study revealed that more than half of the nurses suffered sleep deprivation and made more mistakes related to patient care (Johnston, Arora, King, Bouras, Almoudaris, Davis & Darzi 2015:75).

3.8.1.4 Patient care and human error

Healthcare processes have results which include favourable and adverse changes in health status that can be attributed to health services (Heslop & Lu, 2014:2469-2482). These include self-care; health-promoting behaviours; functional status; complications and adverse events;

symptom management; knowledge of disease and treatment; satisfaction with care; health-related quality of life (Heslop & Lu, 2014:2469- 2482). In addition, staff motivation is important in the HEs as it may lead to organisational commitment and quality patient care. Openness and transparency between the HE managers and employees can also contribute to a conducive work environment (Halldorsdottir, Einarsdottir & Edvardsson, (2018:397)

3.9 ORGANISATIONAL FACTORS

Organisational factors are those factors that include leadership, resource management, legislation that guide the HEs and decision making (Uramatsu et al., 2017:7). Heslop and Lu (2014:2469-2482) state that organisational factors include patients, budget, staff and patient support system. In addition, the HE's objectives, mission, information from the operational environment and strategic plan are amongst organisational factors that should be in place and guided by a Generic Reference Model (Hitchins, 2014:3). Donabedian (1990:1117) emphasises that healthcare standards should be in a framework that is supposed to be in place in any HE for the improvement of healthcare or the wellbeing of the patient.

3.9.1 Standards

The structure, process and outcome standards should be in place at any HE (Donabedian, 1990:1117). Furthermore, standards form part of the monitoring and evaluation process that are aimed at quality care improvement (Joint Commission, 2017:3). Also, standards can be used to reflect on desired and attainable goals in nursing practice (Tenn., 2014:3).

3.9.1.1 Structure standards

Structure standards include staff mix; staffing norms; accredited HE and healthcare delivery model (Heslop & Lu, 2014: 2469-2482). Donabedian (1990:1117) further explains that issues such as facilities, resources, equipment, patient occupancy, availability of staff and nursing management refer to structure standards. Additionally, management structure, mission and vision statements, human resources and team building are important factors that can assist ineffective leadership and management (Polis, Higgs, Candidate, Manning, Gayle, Fernandez, 2017:19-25).

Professional standards guide the HE managers on how to ensure that there are acceptable staffing norms, resources, nursing practice standards, and how nurses should conduct themselves in the nursing profession (Davis, 2014:1-4).

3.9.1.2 Process standards

Process standards are actions taken in nursing practice to perform nursing care and may include procedure manuals, nursing care plans, guidelines and policies (Donabedian, 1990:1117). In

addition, the care plans should include clinical decision-making that is guided by existing research findings and best practice guidelines (Bakerjian & Zisberg, 2013:02-11). Nurses should make decisions and should be accountable for the decisions taken (Davis, 2014:1-4).

3.9.1.3 Outcome standards

Outcome standards are expected outcomes of care that relate to the measurement of care provided and expected performance after quality care is rendered (Donabedian, 1990:1117). Heslop and Lu, (2014: 2469-2482) explain that patient satisfaction surveys, audits, monitoring and evaluation of infection rates, adverse events negative incidents are outcome standards.

3.9.1.3.1 Patient-centred outcome standards

Outcome standards are patient-centred, set to achieve best outcomes designed that risks are minimised in the HE (Davis, 2014:1-4). However, improved patient care cannot be achieved without community diagnosis, through which healthcare needs are identified (Salmond & Echevarria, 2017:12-25). Salmond and Echevarria (2017:12-25) further explains that community needs should be aligned to HE needs to achieve the desired outcomes

3.9.1.3.2 Employee centred outcome standards

Adverse events and employee satisfaction form a part of outcome standards (Heslop & Lu, 2014: 2469-2482). There should be methods to measure if the set standards are achieved or not (Davis, 2014:1-4). This can be done by conducting patient satisfaction surveys.

A study that was conducted to measure the job and practice outcomes revealed that nurses were satisfied with the salaries they received, resource availability, management support systems, parking and team efforts (Amakali, 2015:1-5). Research findings of the study conducted by Halldorsdottir, Einarsdottir and Edvardsson (2018:397) revealed that after the implementation of change employees experienced tension, diminished organisational loyalty, resistance to change, increased stress and fear of dismissal.

3.9.2 Leadership

3.9.2.1 Leadership and latent failures

Reason (1990:8) emphasises that within a HE there are latent failures that are referred to as holes in different Swiss cheese slices. Latent failures may lie undetected for some time until nursing care is affected (Reason, 1990:8). Organisational commitment and leadership are the foundation for mitigating patient harm (Sherwood, 2015:734). The Swiss cheese model provides an opportunity to investigate and address latent failures (Raheja & Escano, 2011:2). Thus, measures taken to improve the quality of care outcomes are important.

3.9.2.2 Leadership and system failures

Managers should understand that the occurrence of adverse events relates to management system failure rather than negligence and incompetence of staff (Coli, Anjos & Pereira, 2010:324-30). Identifying health system failures and the adoption of preventive measures thereof should be considered rather than blaming staff members for adverse events (Coli et al., 2010:324-30). Sherwood (2015:734) further explains that latent failures are sometimes triggered to the extent that system failure is exposed which results in a near miss or adverse events. Unavailability of effective succession planning and poor teamwork have been identified as amongst the factors that may lead to system failure (Dyess, Sherman, Pratt & Chiang-Hanisko, 2017: 309-310).

3.9.2.3 Remedial action to system failures

It is a responsibility of HE managers to ensure that there is employee support systems in place, and trusting relationships exist between employee and employer (Sherwood, 2015:734). Employee- employer relationship may create a conducive environment and staff commitment to their work in HE relationship between leadership styles and staff (Asiri et al., 2016:5).

Safety culture should be implemented that is characterised by positive attitudes, good behaviours and positive mind-sets (Sherwood, 2015:734).

3.9.2.4 Leadership and staff confidence

Formal education that the nurse undergoes to be a qualified nurse is not sufficient for the newly qualified nurse to be confident enough to practise in the nursing profession (Démeha & Rosengren, 2015: 892). The transition period from being a nursing education undergraduate student and being a newly qualified nurse can be a stressful experience that requires mentoring and coaching (Dillon, Dolansky, Casey & Kelley, 2016:173). Instilling confidence amongst the staff members remains important in healthcare practice (Department for Professional Employees, 2016:1). There is a need to bridge gaps that exist between clinical exposure and theory leaning (Démeha & Rosengren, 2015:892). This can be achieved by doing orientation and induction, mentoring and support of the newly appointed staff (Dillon et al., 2016: 173).

The results of a study that was conducted to describe nursing students' experiences of clinical leadership during their last year of education revealed a better understanding of the transition process, from student to becoming a registered nurse (Démeha & Rosengren, 2015:892).

A study conducted on medical-surgical nurses to investigate perceived self-confidence and leadership abilities revealed that nurses who displayed strong leadership abilities were more confident about responding to the deteriorating patient.

3.9.3 Team building

Teambuilding involves teamwork whereby team members can work together to achieve a common goal (Sherwood, 2015: 736). Sherwood (2015:735) emphasises that in a team-building group members have complex interpersonal relations, respect each other, share expertise and support.

Polis et al. (2017:19) substantiate that effective team building and quality patient care are critical components of patient safety at any HE. Thus, the teams should be coordinated around the patients' needs and diagnoses (Dempsey & Reilly, 2016: 8-17). Additionally, effective teamwork and communication may result in quality patient care and less staff turnover (Polis et al., 2017:3). However, healthcare professionals in some HEs are still working in silos (Edmondson, 2015: 1). Consequently, this may lead to poor communication that may eventually compromise patient safety (Edmondson, 2015: 2).

3.9.3.1 Effective team building

The ability of a manager to build a team effectively is the best strategy for quality patient care. Managers have a responsibility of ensuring that staff members work together irrespective of culture, age and nationality and favouritism should be avoided at all costs (Moore et al., 2016:2). Thus, the identification of factors that are important for team effectiveness may assist the managers in developing improvement strategies in service delivery (Polis et al., 2015: 20). Strategies such as building trust amongst the team members, group support, effective communication and interpersonal relations are critical for team effectiveness (Dempsey & Reilly, 2016: 8-17). Good quality care outcomes may be achieved if a multidisciplinary approach is implemented.

Consequently, it may lead to effective team building where healthcare members such as nurses, physicians, radiographers, dietitians and other healthcare members work as a team (Bender, 2017: 190). In addition, collaboration of healthcare services and proper communication are crucial in ensuring quality care (Bender, 2017:190). Team members who have different experiences, views and attitude can sometimes be creative, cohesive and adapt to challenges easily (Moore et al., 2016:2).

3.9.4 Work environment

Aiken, Sermeus, Van den Heede, Sloane, Busse, McKee, Bruyneel, Rafferty, Griffiths, Moreno-Casbas, Tishelman, Scott, Brzostek, Kinnunen, Rhead, Msenior, Zikos, Sjetne, Smith & Kutney-Lee (2012:1-14), explain that a HE environment should be a setting where nurses can achieve the HE's goals and gain personal satisfaction. In addition, the work environment where nursing duties are executed should be conducive to quality patient care (Kieft et al., 2014: 4).

3.9.4.1 Patient care and work environment

Nurses are in contact with patients 24 hours for 7 days a week in the HE environment which allows them to gather much information from their patients (Kieft et al., 2014:3). A safe environment and fewer incidents may result in better outcomes of nursing care (Johnson et al., 2014:17-22).

A study that was conducted in various Dutch healthcare settings identified the nurse's views on how their work and their work environment contribute to positive patient experiences (Aiken et al., 2012:1-14). The results of this study revealed that many factors contribute to the provision of high-quality patient care (Aiken et al., 2012:1-14). The contributing factors include clinically competent nurses, collaborative relationships, autonomous nursing practise, adequate staffing, adequate equipment, control over nursing practise, managerial support and patient-centred care (Aiken et al., 2012:1-14).

3.9.5 Equipment

Management and leadership responsibilities include ensuring that there are proper distribution and utilisation of resources in their HEs (Hitchins, 2014:4). Lack of equipment in any HE may lead to health risks and the inability of the nurses to perform their duties as per acceptable standards (Sherwood, 2015:734). Also, inappropriate use of equipment can compromise patient safety in HEs (Almeida, Neves, Souza, Garcia, Lopes & Barros, 2012:3). Measures that can assist managers in anticipating and identifying errors should be in place in the HEs (Nascimento & Travassos, 2010:625-51).

3.9.5.1 Handling and improper use of equipment

Failure to adhere to HE standards concerning the handling of equipment and equipment failure have been identified as contributing factors to the occurrence of the adverse events (Ribeiro, Silva & Ferreira, 2017:915). However, some studies have identified that in a HE human beings are fallible and can make mistakes to regarding the handling of equipment (Nasciment & Travassos, 2010:625-51). In addition, errors such as improper handling of equipment may be listed as a latent factor (Marin, Patricia, Lopez, Errera & León, 2010:71-84).

A retrospective study conducted in 2010 at Colombian Hospitals revealed that the main cause of 29 adverse events was the improper use of equipment (Marin et al., 2010:718-84). Improper handling of equipment can be linked to a lack of training in using equipment, fatigue and lack of attention by staff members (Johnson, Jun, Song, Brown, Weaver, Richards, 2014:17-22).

3.9.5.2 Lack of equipment

Failure to distribute resources properly in HEs is not a good sign of patient advocacy (Jones, 2016:18). Also, a lack of appropriate equipment to perform certain skills in a HE may lead to adverse events (Johnson et al., 2014:17-22).

A study conducted in one of the hospitals in the United States identified that nurses had to improvise because proper equipment to perform a hysterectomy was not available, and this led to a patient developing pulmonary embolism (Johnson et al., 2014:17-22). The nurse managers must ensure that health resources are available (Jones, 2016:18).

3.9.5.3 Staff training and equipment maintenance

It is advisable that formal training to all staff members regarding the proper use and maintenance of equipment is practiced in the HEs (Beydon, Ledenmat, Soltner, Lebreton, Hardin & Benhamou, 2010:364-72). Staff training about equipment use may provide clarification of doubts and promote the best scientific evidence in nursing practice (Beydon et al., 2010:364-72). There is a belief that nurses are dependent on machines to ensure that the patients are assessed properly (Massey et al., 2016: 6-23). Thus, proper technical maintenance of equipment, proper infrastructure and verification of equipment during shift handover may reduce the occurrence of risks during patient care (Ribeiro et al., 2017: 291).

3.9.6 Staff

Adequate staffing remains key to quality patient care and nurse retention (Department for Professional Employees, 2016:1). Staffing, quality care, patient safety and work environment are all critical factors inpatient care (Dempsey & Reilly, 2016: 8-7).

3.9.6.1 Shortage of staff

Shortage of staff may affect service delivery in any HE (Wagner, Merten, Zwaan, Lubberding, Timmermans & Smits, 2016:3). In addition, researchers discovered that patient survival rates improve with higher numbers of nurses allocated in a unit (Wagner, 2016:13). This is attributed to the fact that they get enough time to spend with critically ill patients (Li Goh, Ang, Chan, He & Vehviläinen-Julkunen, 2018:692-713).

3.9.6.2 Shortage of staff and workload

A balanced patient-nurse ratio is required in a busy nursing unit so that quality patient care is rendered (Li Goh et al., 2018:692-713). However, the number of nurses allocated per nursing unit depends on the severity of patients' illnesses (Papastavrou, Andreou, & Efstathiou, 2014 3-25). Aiken, Sloane, Griffiths, Rafferty, Bruyneel, McHugh and Sermeus (2016: 559) emphasise

that good staffing norms will prevent adverse events, patient dissatisfaction, nurses' dissatisfaction and promote patient safety.

3.9.6.2.1 Effects of staff shortage

Failure to meet patients' expectations, such as being there for them may lead to patient dissatisfaction and unwillingness of patients to recommend the HE to others (Li Goh et al., 2018:679). A study that was conducted in United States of America revealed that a nurse who was overworked erroneously administered insulin instead of giving a patient an antiemetic drug and this resulted in a coma (United States of America Department of Health and Human Services, 2016:3).

It is substantiated that, manageable workload and conducive work environment have good patient care outcomes (Wagner et al., 2016:3).

A study that was conducted in 11 hospitals in the United States over two years revealed that for every 20% decrease in staffing norms, medication errors increased by 18% (Department for Professional Employees, 2016:1).

3.9.6.3 Effects of poor staffing norms

Poor staffing norms may lead to nurses 'overload, and nurses are bound to make errors (Duffin, 2014:2). Coventry, Maslin-Prothero and Smith (2015: 15-25) further explain that increased workloads, poor quality and quantity of work, nurse-patient ratio and high patient acuity contribute to poor patient care and nursing in-service. Difficulties in obtaining time off and increased workload may result in occurrence of adverse events in the HE (Coventry et al., 2015:15-24). Roch, Dubois and Clarke (2014: 229-240) emphasise that poor staffing norms, unsafe working environment and increased workload may result in increased mortality rate and medical errors. A study that was conducted to identify the best evidence on the impact of healthcare organisations' supply of nurses and nursing workload revealed that the heavy workloads, inappropriate, nurse-patient ratios, overtime, time pressure and increased documentation, are the factors linked to dissatisfaction, exhaustion, stress and undesirable levels of care (Rivaz, MaRzi, MoMEnnaSab, Ektatalab & Ebadi, 2017:1). Nurses may likely lack a sense of patient care due to work overload and staff shortage (Roch et al., 2014:229-240)

3.9.6.4 Staff and work experience

Duarte et al. (2015:136-54) identified that a lack of work experience amongst the health workers might lead to the occurrence of adverse events. Highly experienced nurses who have a depth of knowledge can support and mentor the newly qualified nurses (Concordia, 2016: 2). In a survey conducted, Duarte et al. (2015:136-154) found an association between the nursing team's lack

of experience and the occurrence of adverse events in an intensive care unit. The negative effect of inexperienced nurses on healthcare quality attributed to 1,472 incidents related to medications, airways, equipment and procedures. A study that was conducted to identify the relationships among personal resources prior experience in intensive care unit (ICU) / emergency department revealed that nurses with more than 4 years and those that had 0 years of work experience had a less successful transition and retention in ICU / Emergency department (Dillon et al., 2017:173). The first ten years of nursing practice is a period where newly qualified nurses gain knowledge and skills (Dyess et al., 017:309-310). Dyess et al. (2016:309-310) substantiate that it is critical that orientation and induction are done properly at this time so that the skills and knowledge are mastered (Dyess et al., 2016:309-310).

3.9.7 Skills, in-service education and qualifications

3.9.7.1 Skills

Professional development, professional accountability and expert skill development are essential for the patient safety environment (Coventry et al., 2015: 15-24).

Some programmes were initiated to improve non-technical skills performance in HEs (Uramatsu et al., 2017:7). Unfortunately, most studies were unable to report any direct improvement in outcomes for patients, except 15 studies that reported a reduction in time in the resuscitation room and before starting key investigations (Uramatsu et al., 2017:7). Additionally, 16 of 34 cases related to non-technical skills were identified as the cause of death, of which 14 cases (41.2%) were related to situation awareness problems, eight (23.5%) with team working and three (8.8%) with decision making (Uramatsu et al., 2017:7).

A study that was done to identify the benefits of professional development revealed that the participants see the opportunity for professional training, learning and development as very important motivational factors for ensuring patient safety in nursing practice (Halldorsdottir et al., 2018, 397).

3.9.7.2 Qualifications

Continued professional development plays an important role in quality patient care (Raheja & Escano, 2011:2). Staff need new competencies and qualifications so that they have the tools and resources to improve (Sherwood, 2015, 736). Nursing is dynamic, and nurse empowerment remains essential so that quality care is delivered (Asiri et al., 2016:3).

Wagner et al. (2016:2-3) in their study conducted in the Netherlands to minimise adverse events in healthcare identified that the scope of practice, qualifications and task allocation were not

considered during the delegation of duties. The study results revealed that human (70%), organisational (17 %) and technical (7%) factors were contributory to substandard care.

3.9.8 Policies

Policies are amongst the enabling conditions for the quality of patient care (Donabedian, 1990:1117). Protocols and policies are used interchangeably in the HEs for the prevention of adverse events (Paull, 2015: 6). Additionally, patient safety is a critical policy issue and patient harm has been part of healthcare in healthcare practice (Slawomirski et al., 2017: 5).

Measures are taken in South Africa to prevent adverse events; hence, there was a decision to develop a policy for patient safety incidents reporting and learning (National Department of Health, 2016:3). The purpose of this policy was to guide the public health sector in management patient safety incident reporting, provision of appropriate feedback to patients, families, support persons, clinicians and the sharing of lessons learned to prevent patient harm (National Department of Health, 2016:3).

Adverse events do occur irrespective of the availability of protocols and policies (Paull, 2015; 6). Furthermore, inefficient or poorly followed protocols are reported to be a contributing factor to substandard care (Hibbert et al., 2015:1-8).

3.9.9 Effective communication

Effective communication is critical in any HE. Lack of support, clashing priorities, lack of proper communication skills and different perceptions may lead to poor communication (Moore et al., 2016:2). The nurse managers should ensure that there are patients-managers - nurses' interpersonal relations so that values and effective communication skills are available in the HEs (Sherwood, 2015: 736). It is further substantiated that an accurate fast-paced communication system is crucial in emergency care units (Jylhä, Mikkonen; Saranto & Bates 2017:30). Polis et al. (2015:1) emphasised that communication has to be consistent and accurate as it involves the conveyance of important information amongst health professionals in HE. Also, a HE requires an information management system that is guided by the laws, policies and technological tools (Jylhä et al., 2017:30).

3.9.10 Budget

The HE Budgets can have an impact on the delivery of healthcare services, either negatively or positively (Raheja & Escano, 2011:1). The results of a study conducted in Holland showed that the HE management was guided by a cost controlling system that was limiting managers to provide an adequate number of nurses that could provide quality care (Aiken et al., 2012:1-14). Furthermore, the participants highlighted two inhibiting factors to quality care, namely cost-

effectiveness and transparency and accountability goals (Aiken, 2012; 4). Consequently, austerity measures may lead to increased workload, poor in-service training for employees and difficulty in the prevention of adverse events (Raheja & Escano, 2011:1).

3.10 SUMMARY

The measures that are required to ensure quality patient care are discussed in this chapter. The international and national perspective about the malpractice litigation and adverse events are also described. The factors that are contributing to the adverse events that lead to malpractice litigation in nursing practice were discussed, and the different adverse events were also discussed in this chapter. The International classification for patient safety (WHO, 2009:1-154), Generic Reference Model (GRM) (Runciman et al., 2006: 6) and the Safety assessment code (SAC) (SA Health Risk Management Framework, nd) were used to guide this study. Through the guidance of this framework the factors that may lead to safe patient care were also discussed in this chapter grouped into principal types. The factors included standards of care (structure, process and outcome standards).

3.11 CONCLUSION

The researcher can safely conclude that patient safety is sometimes compromised in the HE, which has many contributing factors. Compromise patient safety may lead to malpractice litigation that may lead to billions of rand being lost by healthcare sector institutions.

The next chapter, chapter 4, addressed the research methodology which was used to conduct this study.

CHAPTER 4: RESEARCH METHODOLOGY

4.1 INTRODUCTION

In this chapter, the research methodology used in the study to achieve the objectives set out in chapter 1 is described.

4.2 PHASES OF STUDY

The research was carried out in three phases.

4.2.1 Phase 1: Objective 1

A retrospective audit of malpractice litigation trial bundles was conducted using the audit instrument to identify, classify and analyse adverse events and identify contributing factors that had resulted in litigation in the Eastern Cape and Gauteng public healthcare sectors conducted by the PhD student. In this phase the researcher applied a descriptive quantitative design.

4.2.2 Phase 2: Objective 2

Adverse events and contributing factors that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces were compared and contrasted with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces. In this phase the researcher applied a comparative statistical analysis to the data of the private and public sector. The data of the study of the public sector conducted by the PhD student and those of the two studies conducted by the two master's degree students in the private sector specifically in Gauteng and the Western Cape were merged and analysed by applying a comparative statistical analysis.

4.2.3 Phase 3

Objectives 3 and 4 are linked to this phase:

4.2.3.1 Objective 3 Development of guidelines that may contribute to the prevention of malpractice litigation in nursing practice in South Africa.

Guidelines were developed by using the audit results of the trial bundles that identified the adverse events and contributing factors that resulted in litigation in the private healthcare sector of Gauteng and Western Cape and public healthcare sector of Gauteng and Eastern Cape provinces. In addition, identified nursing process practices that had been violated were also used to craft the draft preventative guidelines.

For the purpose of this objective the researcher applied the WHO guideline development process to develop these guidelines which may contribute to the prevention of malpractice litigation in

nursing practice in South Africa (see paragraph 4.5.3.1). The results of phase 2 were used to develop the draft set of guidelines.

4.2.3.2 Objective 4. The validation process of the formulated guidelines

The Delphi method was applied to validate the drafted guidelines.

4.3 PHASE 1.

A retrospective audit of the malpractice litigation trial bundles was conducted to identify, classify and analyse adverse events that had resulted in litigation in the public healthcare sectors of the Eastern Cape Province (ECP) and Gauteng Province.

4.3.1. Phase 1 Objectives:

- To complete an audit of the nursing process documents in the trial bundles
- To determine the principal incident types that were associated with adverse events involving nursing practitioners. The scope of practice, draft regulation R786 of 2013 in terms of the Nursing Act, 2005 (Act No. 33 of 2005) was used to guide this objective
- To determine the factors that were associated with adverse events involving nursing practitioners
- To identify other members of the health service team that were associated with these adverse events. The scope of practice of other healthcare professionals, policies and guidelines guided the researcher.
- Determine the severity of the adverse events as defined by the Safety assessment code (SAC) (SA Health Risk Management Framework, nd).

4.3.2 Phase 1: Hypotheses

H0: There are no statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces

H1: There are statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces.

4.3.3 Research design and place of research

A retrospective descriptive quantitative research design was used to conduct an audit on adverse events, which led to malpractice litigation in nursing practice in the Eastern Cape Province in the State Attorney's offices in East London of the Eastern Cape Department of Health Legal Services and in Gauteng Province in the State Attorney's offices in Johannesburg.

The rationale for investigating malpractice litigation in these two provinces i.e. Eastern Cape and Gauteng provinces was because these two provinces have the highest number of malpractice litigation cases in South Africa.

According to the South African Law Reform Commission (2017:16), the two provinces were the highest in principal amounts paid out for litigation on behalf of the Department of Health by the offices of the State Attorney during the financial years 2010/2011 amounted to:

- Eastern Cape: R13 421 136 000,
- Gauteng: R13 452 064 000,
- In 2013/2014 amounted to:
    - Gauteng R 153 612 355.49
    - Eastern Cape R 49 513 108.93
- In 2015-2016 financial year
    - Eastern Cape Province: R 13 421 136 000
    - Gauteng 13 452 064 000
- The National Minister Dr Aaron Motsoaledi reported malpractice litigation of R90 billion pending in March 2019 (SAPA 2019).

The researcher identified the need to compare the two provinces specifically to identify the factors contributing to adverse events that lead to malpractice litigation and that were more likely to occur in each province as these provinces differed in size and resources. Gauteng is the richest province with a GDP of R897,553 million (Richie, 2019) and Eastern Cape the poorest province. According to Statistician-General Pali Lehohlang that of the 6.5 million inhabitants of the ECP 12.7% is “multi-dimensional poor” (DispatchLive, August 2017).

Geographically Gauteng is the smallest province, 18,178 km² in South Africa while the Eastern Cape province is the second largest province with a size of 168,966 km² mostly deep rural, whereas Gauteng is mostly urban (South Africa, 2009:6). The people in the ECP have to travel long distances to reach a HE while in the Gauteng province the HEs are close to residential areas.

It was further identified that the ECP has 830 health establishments widely distributed in the province and Gauteng province has 393 with all HEs based in a smaller geographical urban area. The Office of Health Standards Compliance annual inspection report shows that ECP compliance score was 40% for the financial year 2014/2015 and 73% for the Gauteng province. The adverse events that occurred were reported as 53% in Gauteng and 60% in ECP (OHSC Annual Inspection Report: June 2018).

Thus, despite their unequal differences, both provinces had the highest litigation rates in South Africa. It was against this background the researcher identified a need to compare the two provinces.

The descriptive approach was used to identify and describe the factors that might have contributed to the malpractice litigation in nursing practice South Africa (Omair, 2015:153-6), and to identify problems within clinical practice, and determine what is being done in similar situations (Omair, 2015: 153-6). The researcher applied the descriptive approach to describe what existed and categorise the obtained knowledge (Gray, Grove & Sutherland, 2016:22).

4.3.4 Population and sampling

The study population was the trial bundles that met the inclusion criteria of the study (Dorley, 2019:98).

The target population in this study was completed malpractice litigation cases which occurred in the Eastern Cape and Gauteng provinces in the public healthcare sector from 2006 to 2016. In a court of law, a malpractice litigation case may take up to 6 to 10 years to be finalised. Thus to ensure that an adequate number of cases were selected the timeframe was set to extend from 2006-to 2016.

A power analysis was completed by the biostatistician to determine the number of trial bundles required for the main study.

Based on the primary hypothesis for objective 2, that there is a difference in proportion of litigation cases due to (caused by) enrolled nurses (ENs) and or enrolled nursing assistants (ENAs) versus higher cadres of nurses, between state and private cases, we assumed the prevalence of cases due to EN/ENAs was higher in the private cases than the public cases, as informed by the pilot results. A difference of 12% was deemed the minimum difference of clinical importance. This effect size is able to be detected as statistically significant with sample sizes of 196 in each group with 80% power. This was rounded up to 200 per group, i.e. private and public as the optimum sample size. Thus a total of 400 trial bundles were required to meet this objective.

In the public healthcare sector, the provincial staff obtained all the bundles that they could locate during the period of the study, and these were included in the study population.

The total population which met the criteria consisted of 98 trial bundles from Gauteng and 105 trial bundles from the Eastern Cape healthcare sectors, N = 203. Grove et al. (2014:250) explain that if the total population of a study is too small, it would be advisable to utilise the entire

population, as a sampling of such a small size would not be possible and thus the total population of trial bundles made available to the researcher were included in the study.

4.3.5 Sampling criteria

Sample criteria were all completed cases collected over 11 years, from 2006 to 2016.

4.3.5.1 Inclusion criteria

Inclusion sampling criteria are characteristics that the element or subject must possess to form part of the target population of the study (Grove, Gray & Burns, 2014:251). Malpractice litigation cases, either heard in the South African High Courts or settled out of court in South Africa, specifically litigation cases which involved the public healthcare sector within the Gauteng and Eastern Cape provinces were included in the study.

4.3.5.2 Exclusion criteria

Exclusion criteria are characteristics which allow the researcher to exclude an element or a person from the target population (Grove et al., 2014:251). The researcher excluded malpractice litigation cases that had received media coverage occurring in the public healthcare sector in the Gauteng and Eastern Cape provinces. Any malpractice litigation case that was used in the pilot study, involving the road accident fund, labour-related issues and those which occurred in the private healthcare sector was excluded.

4.3.6 Pilot study

Chen and Tat (2016:1667-1671) define a pilot study as a mini-replica of the proposed study and completed in the same way the actual study was done. A pilot study assists in identifying any problems with the design of the study, allows the researchers to familiarise themselves with the subjects, the setting and the methodology (Gray et al., 2016:22).

The pilot study was conducted for the main study consisting of n=42 (10.5%) of the 400 trial bundles determined for the study. The legal and clinical records of 42 trial bundles of cases which were either heard in South African high courts or settled out of court provided the opportunistic cohort for the pilot study. The trial bundles of cases over a period of 11 years (2005-2015) from predominantly attorneys and advocates in Kwazulu-Natal, Gauteng and Western Cape were used to obtain clinical, legal and circumstantial data surrounding each case. Due to the difficulty in obtaining trial bundles all available trial bundles obtained from lawyers were included. An opportunistic sample included trial bundles obtained from Gauteng, Western Cape and Kwa-Zulu Natal provinces which included private and public healthcare sectors contributed to the pilot study.

The audit instrument was used to conduct a retrospective audit of malpractice litigation cases in nursing practice in South Africa, which was designed to meet the study objectives. After the completion of the audit instrument as discussed in paragraph 4.3.7 the pilot study started when 42 trial bundles were audited. The PhD student and two master's degree students each had 14 trial bundles to audit. Each sub-investigator audited their trial bundles with the principal researcher. Data was captured in a spread sheet and analysed. Guided by the biostatistician specific codes were given to ensure clarity about what was not applicable and what was not done. The results showed that the private sector was more likely to settle a case while in the public sector cases were more likely to be presented in court. A presentation of these results was made at a conference and prepared for publication.

4.3.7. Reliability and validity

4.3.7.1. Reliability

Rigour of the study should be considered when conducting research and it is achieved by measuring validity and reliability (Zhong, Zhao, Wu, Xiao, Tan & Zhang, 2019: 11762-11769). According to Burns et al. (2016:390) reliability denotes the consistency of measures obtained in a particular instrument and indicates the extent of random error in the measurement method and reliability questions the measures of consistency within the study (Zhong et al., 2019: 11762-11769).

The reliability of the audit instrument was tested during the pilot study and the design of the instrument by applying the test-retest method to ensure that the instrument contained all the required information to complete an audit of the adverse events, and will thus be able to produce consistent results when used by other researchers, in similar conditions (Zhong et al., 2019: 11762-11769).

The audit instrument used in the pilot study was developed for both private and public healthcare sectors. However, for use in the public healthcare sector only it was adapted to exclude reference made to private.

4.3.7.2 Validity

The content validity approach, as suggested by Gray et al. (2016:22) was used to determine the extent to which all major elements of the construct were measured. According to these authors, an instrument determines the extent to which it reflects the abstract construct being examined, and the extent to which the measure used by the researcher is valid for its intended purpose (Chen & Tat, 2016:1667-1671). For the purpose of this study the audit instrument was based on

the trial bundles, theoretical framework and literature of the study and thus met all the major elements of the construct to be measured.

Face validity was also assessed to determine whether the audit instrument measured the content it was supposed to measure (Zhong et al., 2019: 11762-11769). Face validity of the study was supported by the guidance of the experts in the field of quality assurance, specifically the quality and safety of patient care. The co-supervisor of this study is an international expert in quality assurance, and the supervisor is an expert witness in malpractice litigation with her focus area in quality and safe patient care. Furthermore, the biostatistician, a co-investigator of the main study, has enhanced the face of the study.

Initial requests to especially the three large private health organisations to participate in the study were declined. Furthermore, the trial bundles were confidential and only the researchers, co-researchers and sub-investigators who signed a declaration with HREC were allowed to access a trial bundle. Providing input into the audit instrument required a participant to work through the trial bundles. This would only have been possible if the private sector gave permission to have their own trial bundles to have been audited. Each organisation could then have given input on their own trial bundles. In this study trial bundles were only obtained from lawyers which were confidential. The rigour of this study was further enhanced by conducting the pilot study of this study, as explained in paragraph 4.3.6. The principal investigator of the main study carried out data collection training, and the PhD student was trained. In addition, the principal investigator validated 35% of the PhD students' data collection in Gauteng province to ensure the validity of the study. This was done by cross checking of the questionnaires and trial bundles that were audited

4.3.8 Instrumentation (Annexure 1)

The instrument was designed to meet the study objectives. To meet these objectives, the audit instrument was based on the literature, malpractice litigation trial bundles which included the nursing process and scope of practice of nurses, theoretical framework, SAC and critical realism theory discussed in chapter 2 as applied for the purpose of this study.

Table 4.1. Audit instrument development based on literature and theoretical framework

Audit instrument	Literature review	Theoretical framework, sac, nursing process & scope of practice
SECTION A : Litigation	Paragraph : 3.2	
Section B –D : Clinical management (including nursing process and theatre)	Paragraph :3.6 Nursing process, Paragraph :3.7 Clinical management	Nursing Process, international classification for patient safety model

		and Generic reference model The scope of practice, draft regulation R786 of 2013 based on the Nursing Act, 2005 (Act No. 33 of 2005)
Section :E :Adverse events (SAC in Section F)	Paragraph 3.3.	SAC,
SECTION F: Principle types and factors contributing to the adverse events	Paragraph 3.4 & 3.5. Principle type, Leadership, management and administration Human behaviour: 3.8 Organisational factors : paragraph :3.9	The international classification for patient safety model and Generic reference model

The instrument was written in English since all the malpractice litigation cases were conducted in English.

The principal researcher together with the sub-investigators i.e. the two master's students and PhD student worked on developing the audit instrument. The principal investigator worked through 42 trial bundles to have a first draft of the audit instrument. Followed by this activity, each sub-investigator had fourteen trial bundles to work through to check with the principal researcher aspects they identified that should be added or rephrased.

The final draft instrument was then checked by the co-researchers: the biostatistician, co-supervisor, an expert in quality assurance and a specialist in writing standards. After their feedback changes were made as suggested. Multidisciplinary expertise should be sought to interrogate the questionnaire, decide if it covers what it seeks to achieve and modify the same accordingly (Chen &Tat, 2016:1667-1671). This process took at least eight (8) months. The instrument was applied in both public and private healthcare sectors.

The audit instrument was divided into six sections containing 40 questions to guide the auditing process.

Objectives 1 and 2 of the study were linked to the instrument as follows:

- **Section A**: Includes questions regarding the litigation
- **Section B**: Demographic data of the patient
- **Section C**: Questions describing the hospitalisation period
- **Section D**: Operating room information
- **Section E**: Adverse event(s) information

- **Section F**: Principal incident type, the severity of adverse event and factors contributing to the adverse event.

Section A-D included the assessment of the nursing records and auditing of patient care plans and treatment reports, which included details pertaining to the litigation, the demographic information of the patient, hospitalisation period and operating room information (if applicable to the individual case).

Section E: described the details regarding the adverse event. This included the environment where the adverse event occurred, the outcomes experienced by the plaintiff, as well as the members of the multi-disciplinary health team that may have played a role and the severity of the adverse event.

Section F: identified the adverse event according to its principal incident type, indicated the severity of the adverse event according to the Safety Assessment Code (SA Health Risk Management Framework, nd) and identified the factors that have contributed to the adverse event.

4.3.9 Data collection

The quantitative descriptive data collection method applied in the study was designed to resonate with the research design and measurement techniques as recommended (Omair, 2015: 153-6). The assumption was that a quantitative approach is objective and remain neutral to avoid bias, as described by Antwi and Kasim (2015:218).

The researcher ensured that precautionary measures were taken during data collection to avoid getting unreliable findings.

The researcher personally collected the data in the Gauteng and the Eastern Cape from the State Attorneys' Offices. The data collection process began once ethics approval and a waiver of consent had been granted to audit the malpractice litigation bundles. Audits took place at the offices of the state attorneys and legal services in the Eastern Cape and Gauteng provinces with a condition that no information was taken out of the offices either by taking pictures or removing the files covering Gauteng and Eastern Cape provinces over eleven years from 2006-2016. The master's degree students individually collected data from the different law firms in Gauteng and Western Cape provinces under similar conditions.

The data collection took place in Bisho and East London in the Eastern Cape. It commenced in Bisho in November 2017 and was completed in January 2018 during which 105 trial bundles were audited.

Data collection in Johannesburg in the Gauteng Province commenced in September 2018 and was completed in January 2019 during which 98 trial bundles were audited. Thus a total of N=203 trial bundles were audited.

The number of pages in the malpractice litigation trial bundles ranged from 200 to 3000 pages and included expert witness opinions, clinical records as well as statements from the plaintiffs and defendants.

The researcher encountered many challenges during data collection, which included the filing system that was not arranged systematically.

All malpractice litigation cases aligned with the criteria were used in the study and data was collected anonymously.

The data collection tool was not labelled or marked with any reference to the specific case but was given a unique number to capture in Excel spreadsheets for checking and to keep track of the number of bundles audited.

4.3.10 Data analysis

Quantitative data analysis was used in which data was converted to a numerical system and analysed statistically (Ali & Bhaskar, 2016: 662–669).

Descriptive statistics were used in this study to describe the data collected by summarising information that emphasises the important numerical features of the data of this study (Antwi & Kasim, 2015:218).

The collected numerical data were analysed using mathematically based methods using the Statistical Package for Social Sciences (SPSS) version 25. The applied SPSS produced charts, tables, as well as numerical statistical measures that required interpretation (Kühberger, Fritz, Lermer & Scherndl, 2015:5).

Statistical tests were applied to determine statistical differences, which included the Chi-square Pearson test. Statistical associations were identified to determine whether there were statistical differences between the variables using a 95% confidence interval. For this study, a p-value of ($p \leq 0.05$) was used to determine statistically significant differences between variables.

The data that were obtained from the trial bundles were analysed with the support of a bio-statistician.

The analysed data is presented in chapter five in frequencies, organised using figures and tables to provide a visual representation and descriptive information according to the results of each question in the audit instrument, in line with the objectives of the study.

4.3.11 Ethical considerations

Ethics approval was obtained from the Faculty of Medicine and Health Sciences at Stellenbosch University which included a waiver of consent that allowed the researcher to audit the trial bundles without the plaintiffs' or defendants' permission (Ethics Committee approval number N16/02/027A - Annexure 2).

Permission was obtained from the Eastern Cape Health Research Committee reference number (EC_2017RP12_126 -Annexure 3) to access the malpractice litigation trial bundles, from the Head of Legal Services Eastern Cape Department of Health and the Head of the State Attorney's Office East London (Annexure 3). The Ethics approval was obtained from the Eastern Cape research committee in August 2018 and in October 2018 from Legal Services Department of Health.

In Gauteng, permission was obtained from the Gauteng Department of Health Provincial Protocol Review Committee reference number (GP2027R23153 Annexure 4)

Permission to access the files in Gauteng Province was granted by the Acting Chief Litigation Officer of the State Attorney's Offices South Africa (Annexure 5).

The researcher arranged appointments with the heads of the:

- State Attorney's Offices in East London
- State Attorney's Offices in Mtata
- Legal Services Office at Bisho.

The researcher personally visited the State Attorney's National office in Pretoria to request permission to access the files.

The offices were chosen after the researcher was advised that these were the offices that had large numbers of completed malpractice litigation cases. The heads responded positively to the request to audit the malpractice litigation bundles.

The confidentiality, privacy, dignity and respect to human rights of the defendants and plaintiffs were maintained. Auditing the malpractice litigation bundles took place at the attorney's offices. The researcher ensured that the names and any reference to place of the plaintiffs, HEs, lawyers and defendants were kept confidential. The researcher collected data at the offices of the state

attorneys and legal services and neither photos, nor documents were taken out of the data collection setting.

4.4 PHASE 2: OBJECTIVE 2

During this phase objective 2 was completed namely a comparative statistical analysis of the adverse events that led to malpractice litigation of cases in the private healthcare sector in Gauteng and Western Cape provinces audit by two masters' students and malpractice litigated cases in the public healthcare sector in Gauteng and Eastern Cape provinces audited by the PhD student were carried out.

4.4.1 Phase 2: Hypotheses

The following hypotheses were set for this phase.

H_0: There are no statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice between the public and private healthcare sectors.

H_1: There are statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice between the public and private healthcare sectors.

4.4.2 Data analysis

The spreadsheets that contained data collected from three studies were merged and aligned, applying the SPSS statistical tests which included the Chi-square Pearson to determine the statistical differences between the private and public healthcare variables using a 95% confidence interval.

A p-value ≤ 0.05 was used to determine statistically significant differences between variables. Multiple tests were done in this study to achieve the objective namely "To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces. This objective was stated a priori in the research proposal and thus were pre-planned tests rather than post hoc tests. The protocol was accepted and approved by the Faculty of Medicine and Health Sciences at Stellenbosch University Ethics Committee and the PhD advisory committee. Statistically significant ($p<0.05$) associations identified in the results chapter have been examined for presence of clinical significance in the interpretation of the results. Additionally, type 1 error is not common where sample size is relatively small such as in this study, where large clinical differences were required before statistical significance was achieved. The possibility of type 1 error after taking these three points into consideration is acceptably low in this study.

The analysed data obtained in the public healthcare sector is presented in chapter five. The comparative analysis between the public and private healthcare sectors are presented in chapter 6. Results are presented in frequencies, organised using figures and tables, providing a visual representation and descriptive information according to the results of each question according to the audit instrument.

4.5 PHASE 3

The purpose of phase 3 was to develop and validate a set of guidelines which may contribute to the prevention of nursing malpractice litigation in South Africa based on phase 2. This phase is linked to objective 3 and 4 of the study.

4.5.1 Introduction

A set of guidelines is a document with either clinical, public health or policy interventions that contain recommendations about health interventions (WHO, 2010:4). This document should provide guiding information about what is expected of policymakers, healthcare providers or patients and implies a choice between different interventions that have an impact on health (WHO, 2012:4). The purpose of guideline development is to improve the quality of healthcare delivery (Vermeulen, D'Angelo, De Sutter & Nelen, 2014:15).

The development of guidelines should follow specific rules to avoid disagreement, misunderstanding, misleading recommendations and confusion (Pringsheim & Addington, 2017: 586-593). These are systematically developed statements aimed at assisting healthcare providers in making proper patient care decisions (Vermeulen et al., 2014:7).

Guideline development, implementation and evaluation interdependent are activities with different steps to be followed (Vermeulen et al., 2014: 5). WHO (2012:11) stated that several steps are required for guideline development.

In this study validated guidelines were developed according to the WHO guideline development process (WHO, 2012:11) as set out in table 4.2. The purpose of these guidelines is to contribute to the prevention of malpractice in nursing practice litigation based on the comparative analysis described in phase 2.

4.5.2 Rationale

The researcher has indicated as described in paragraph 1.2 that there are multiple factors that lead to malpractice litigation hence the development and validation of guidelines that will contribute to the prevention of malpractice litigation.

4.5.3 Objective 3: Development of guidelines that may contribute to the prevention of malpractice litigation in nursing practice in South Africa

The development of guidelines to contribute to the prevention of malpractice in nursing practice litigation are described in table 4.2.

4.5.3.1 The guideline development process

The WHO guidelines development process (WHO, 2012: 11) was applied to develop guidelines. The development was descriptive and based on the results obtained from a comparative analysis that was completed in phase 2 of this study. The completed guidelines provide a description of the exact methodology followed, including the processes of convening the author panel, performing the literature search, and reviewing the evidence (Petersen, Lopez, Armstrong, Getchius, Gronseth, Marson, Pringsheim, Day, Sager, Stevens & Rae-Grant, 2018: 126-135).

The steps twelve steps as shown in table 4.2 were followed. The Guideline Development Group was formed as described in table 4.2. Based on the evidence obtained in phase 2, the guidelines were developed according to the principal types i.e. clinical management, leadership, management and administration and behavioural management. The development process was done via email. The literature search that was conducted for this study also guided the GDG to develop the guidelines. Draft guidelines were sent to the GDP for comments until the group reached the consensus were acceptable for the validation process. The development process was followed as shown in table 4.2.

Table 4.2: Application of 12 steps of the draft guideline development process

Steps that were followed in the development of the draft guidelines	Action
1. Guideline topic selection	"Validated guidelines that contribute to the prevention of malpractice litigation in Nursing Practice in South Africa" was used as a guideline title
2. Development of the guideline development group (GDG)	Members that formed the GDG team were formed as follows: A team of researchers who are experts in the field of quality assurance specifically quality and safety of patient care and involved in the main study and sub-studies were invited to be members of the GDG. The group consisted of the following experts: • co-supervisor in the PhD study who is an expert in quality assurance and writing guidelines in quality assurance, • an expert in accreditation and policymaking in healthcare and quality assurance • the principal investigator is an expert witness in malpractice litigation with her focus area in quality and safe patient care • a biostatistician who is a co-investigator of the main study • PhD student, a sub-investigator of the main study and chairperson of the GDG.

3. Selection and invitation of the GDG members	The experts in the field of quality assurance and patient safety who were members of the GDG were selected and invited via emails to participate in the development process of the guidelines.
4. Scoping of the guideline	The guideline objectives were defined, based on objective 2 of this study of which the similarities and differences were identified. After consensus on what is within and outside the scope of the guideline was reached, the range was defined according to a checklist designed by the GDG and evaluated for completeness and feasibility. Once the scoping was complete, the guideline questions were developed.
5. Development of the key questions	The developed key questions were clear, focused and defined the boundaries of the topic. Questions such as: What is the purpose of these guidelines, what are the factors that contribute to the adverse events that may lead to malpractice litigation in the Nursing practice in South Africa were developed.
6. Search of evidence	The rationale for the study, conducted literature review, the research study results and theoretical framework guided the GDG to develop guidelines. Following this, there was a translation of key questions into keywords, and the search gathered to avoid or minimise bias. The researcher, with the research specialists, selected only the best available evidence.
7. Synthesis of evidence DGD	Guided by the study literature and the study research results, the group identified the most appropriate data.
8. Development of recommendations	Phase 2 guided this step. The group summarised and condensed the evidence content obtained in step 6 into recommendations. When the GDG reached consensus about the development of recommendations, the first draft version of the guidelines was written.
9. Writing the draft version of the guidelines	A comprehensive and flexible guideline draft was written in English. This allowed adaptation to diverse settings and circumstances of clinical practice. Guidelines were written in the following order: • general introduction and scope of the guideline • Drafted guidelines were organised according to the nursing process and adverse principal type.
10. Guideline dissemination	Validated guidelines will be recommended in the dissertation of the PhD study and published
11. Guideline implementation and evaluation	Implementation will be done on a post-doctorate level.
12. Guideline updating	Nursing practice is dynamic; this warrants guideline to be kept up to date at least at three-yearly intervals or as required.

(WHO, 2012:11)

4.5.4 Objective 2: Validation process of the formulated guidelines

4.5.4.1 Introduction

The validation process of the practice guidelines is important to ensure accuracy in the document that is developed for implementation. This process is carried out using different techniques to reach consensus, identify and understand a variety of viewpoints and resolve agreements (Grove et al., 2016:358). Walker, Liu, Kieran, Jabado, Picton, Packer and St. Rose (2013, 462-468) applied this technique to obtain >70% agreement from > 60% of the participants; where <70% consensus occurred, the statement was modified and resubmitted for voting. The process was continued until consensus was reached on all the statements. A similar study was conducted to reach a consensus definition of running-related injury in recreational runners through a modified

Delphi approach (Yamato, Saragiotto & Lopes, 2015:375-385). In this study, the consensus was reached within three rounds. A consensus definition of running-related injury was reached, with 80% of participants (Yamato et al., 2015:375-385). Furthermore, for any quality improvements in an organisation, an informed and consensus-based decision or opinion must be reached about an important organisational issue or problem, such as a policy-oriented issue or managerial problem (Kalaian & Kasim: 2012:2).

The focus in this phase of the study was the validation of the developed drafted guidelines which may contribute to the prevention of adverse events in nursing practice. The validation process was applied using the Delphi technique, and the outcome is discussed in chapter 7.

4.5.4.2 Application of the Delphi method

The criteria set for the consensus Delphi method was set at 80%. By applying this method, it assisted the researcher in understanding and identifying a variety of viewpoints and to reach consensus on the developed draft guidelines (Grove et al., 2016:368). The Delphi technique provided an opportunity for the experts in nursing practice and research to share their expertise so that there is quality care in nursing practice in South Africa. This method is different from other methods as the participants remain anonymous; there is controlled feedback and statistical group responses (2017:6). Explained further, the method could not predict the outcome of the validation process of the guidelines; it just provided an opportunity for the researcher to organise and direct the experts' group opinion (Goodman, 2017:6). A panel of N=107 participants, experts in health care with their focus area being safe quality patient care, was invited to participate in the validation process. The panel was contacted telephonically and by e-mail to confirm availability for the review and validation of the drafted guidelines using a Delphi method. However, only 82 responded to participate in the Delph process. Questionnaires were sent to these experts with the response rate N=60(73%). The panel consisted of experts with various roles as listed:

- Academics in healthcare
- Consultants in health systems
- Participating in the accreditation of hospitals
- Participating in policymaking in healthcare
- Participating in regulating bodies in healthcare
- Writing healthcare standards for health establishments
- Clinical practice.

A questionnaire was developed based on the drafted guidelines. The researcher was guided by the theoretical framework, literature search, phase 2 results and WHO guideline development process to develop the questionnaire that was used to validate the guidelines using the Delphi

method. The supervisor, the co-supervisor of this study and the biostatistician, who is the co-investigator in the main study, gave guidance in the development of the questionnaire.

4.5.4.2.1 Round 1 of the Delphi Technique

A brief background about the study was given in a questionnaire that was developed for round one of the validation processes. It was further stated in this questionnaire that by agreeing to participate, the participant would be regarded as giving informed consent based on the explanation given about the study (See annexure 7).

National and international experts, as described in operational definitions, were invited to participate in this consensus Delphi method on-line survey (Kalaian & Kasim: 2012:1). Three expert reviewers were contacted internationally in Qatar, Germany and Tanzania. In addition, national experts were invited from the nine provinces of South Africa. Participants participated without a meeting, to avoid alteration of individuals' opinions by the persuasive behaviour of a few people at a meeting (Grove et al., 2016:358). The questionnaire was developed through the evidence obtained from the study in phase 2 and the theoretical framework that guided this study (See annexure 7: Round 1 Delphi method questionnaire). Thus, the questionnaire and a participant invitation letter were submitted to individual reviewers. The group of expert reviewers were requested to complete the questionnaire and to either agree or disagree with the drafted recommended guidelines. Following each guideline, some space was provided for additional comments. Experts were given a timeframe of seven days to complete the exercise in round one. The feedback received from individual reviewers was reviewed.

The sections that were addressed in this questionnaire were

- **SECTION A:** Demographic data about the participants
- **SECTION B**: Clinical management

The phases of the nursing process were addressed:

- Phase 1: Subjective and objective information of the patient
- Phase 2: Formulation of the nursing diagnosis
- Phase 3: Planning
- Phase 4: Implementation
- Phase 5: Evaluation

SECTION C: Human behavioural problem

SECTION D: Organisational issues:

- Organisational factors

- Nursing leadership and management
- Operational management
- Continuous nursing professional development
- Nursing monitoring and evaluation

Before the implementation of round one, the draft guideline questionnaire was reviewed by the supervisor, co-supervisor and biostatistician.

4.5.4.2.2 Round Two of the Delphi Technique

A similar questionnaire, as applied in round one, was developed based only on those guidelines upon which the participants commented that the guidelines should be rearranged and rephrased during round one. The questionnaire was only sent to those experts who participated in round one. In round two N=60 who participated in round one was invited to participate. The timeframe of three days to complete the exercise in round two was given. However, an extension of three days was allowed. Thirty-six (60 %) participants participated in round two. The summary of the steps that were followed to validate the guidelines using a Delphi method is described in table 4.3.

4.5.4.3 Data analysis

The researcher consulted a biostatistician to complete statistical analysis on the responses of round one and two. As the consensus of 96%-100% was reached in round 2, the Delphi method was terminated.

Table 4.3: Application of the Delphi technique

1st Round	1.1	Sixty experts in the panel anonymously answered closed-ended questions on the drafted recommended guidelines. Two guidelines scored below 80% in this round were deleted. Furthermore, the participants commented that some guidelines should be rearranged and rephrased during round one.
2nd Round	2.1	The questionnaire was submitted to the same N=60 panel of experts who participated in round one to obtain consensus about the newly developed close-ended questions. In this round, questions that were similar, the participants suggested that it should be deleted.
	2.2	The researcher reviewed and analysed the survey responses from round two to provide a comprehensive description of the experts' consensus and agreement on the validation of the guidelines. This consensus and agreement report were based on the statistical analysis completed on the response of the second round. The supervisor, co-supervisor and the PhD student agreed that the consensus criteria should be reached at 80%. Thus, there was no need for any further rounds of survey administration and data collection. Descriptive data analysis was done; after that, the final recommended validated guidelines were formulated on the outcome of the Delphi method.

(Kalaian & Kasim, 2012:2-3)

4.6 SUMMARY

In this chapter, the research methodology as applied in phase 1 was described, the comparative analysis applied in phase 2 to compare and contrast the private and public sector and phase 3 describing the process followed according to the guideline development and the Delphi method applied to validate the guidelines.

4.7 CONCLUSION

Quantified consensus statements from international and national experts in the field of Nursing practice will act as a basis for further advancing clinical practice and may contribute to the prevention of adverse events leading to malpractice litigation in the nursing profession which lead to malpractice litigation.

CHAPTER 5: DATA ANALYSIS: THE EASTERN CAPE AND GAUTENG HEALTHCARE SECTORS

5.1 INTRODUCTION

The PhD student completed an audit of adverse events, which led to malpractice litigation in the Eastern Cape Province (ECP) and Gauteng public healthcare sector.

In this chapter, the researcher presents a comparative statistical analysis of adverse events that led to the malpractice litigation and covered the demographic features of implicated nurses, and their discipline, the type of ward where the adverse events occurred, nursing procedures not adhered to, and the principal incident type of the adverse event, its severity and contributing factors.

5.2 THE PURPOSE OF THIS CHAPTER

The chapter set out the comparative statistical data extracted from 203 malpractice litigation trial bundles containing nursing documents, complaints from the defendant and the plaintiff sent to the lawyers, notes written by expert witnesses about the aetiology of adverse events recorded in the trial bundles.

5.3 RESULTS OF STATISTICAL COMPARATIVE ANALYSIS

The IBM Statistical Package for the Social Sciences (SPSS) version 25: was used to create charts, tables and numerical statistical measures to assist in the interpretation of the results.

Pearson Chi-Square was used to determine whether there were statistical differences between the variables using a 95% confidence interval at a p-value of ($p \leq 0.05$) to determine statistically significant differences between variables.

The data that was collected in the two provinces were merged to accept or reject the hypotheses that were set for phase 1 of this study:

- H_0: There are no statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces.
- H_1: There are statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces

A brief of key results shows that in the Eastern Cape and Gauteng provinces the data revealed that patients experiencing adverse events were more likely to:

- Be female, between the ages of 16 to 35, single and unemployed. Those that were employed were likely to be unskilled or labours.
- Admitted as an emergency for midwifery or obstetrics to a labour ward.
- Have an incomplete initial nursing assessment and incomplete nursing care plans.
- Have incomplete vital sign monitoring, including incomplete monitoring of blood pressure, pulse, foetal heart rate, respiration, temperature and intake and output.
- Have incomplete laboratory tests including haemoglucotest, blood gases and electrolytes
- Have no patient education on discharge

Eighty percent of patients experiencing adverse events had their quality of life affected with 71% becoming disabled. The principal incident type of 90% of adverse events were classified as due to clinical management. More detail is provided in the sections that follow.

Checking, rechecking and crosschecking of the data were carried out with the assistance of the supervisor who is the principal investigator of the main study. The purpose of crosschecking the data was to ensure the validity of the data that may affect the study. Each column of the tables showing the data were cross-checked with “99” representing “not applicable”. The data not available was collapsed into one column with “not documented” and code “98”. The codes 98 and 99 were used as guided by the biostatistician.

5.3.1 Section A: Litigation (Questions 1-2).

5.3.1.1 Question 1: Province where the malpractice litigation occurred (N=203)

Figure 5.1 shows that n=98 (48.0%) of malpractice litigation cases occurred in Gauteng Province and n=105 (52.0%) in the Eastern Cape.

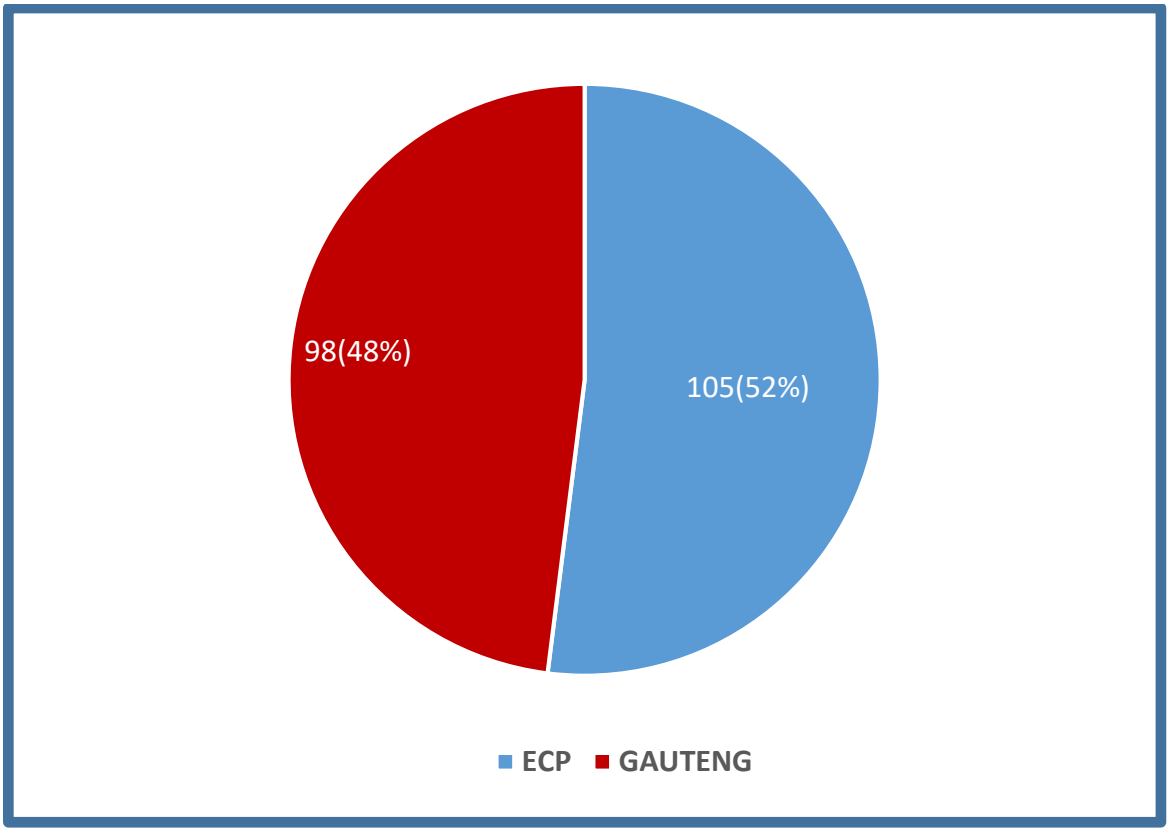

Figure 5.1: Provinces where the malpractice litigation occurred (N=203)

5.3.1.2 Question 2: Case presentation (N=203)

As shown in table 5.1 N=203 (100%) of the trial bundles audited were presented and settled in the different High courts either in Gauteng or Eastern Cape provinces.

Table 5.1: Case presentation (N=203).

Case presentation	Eastern Cape Province (ECP)	Gauteng Province (GP)	Total
	n=105 (52%)	n=98 (48%)	n=203 (100%)
Total	**n=105 (100)**	**n=98 (100)**	**N=203 (100%)**

5.3.2 Section B: Demographic Data (Questions 3 -11)

5.3.2.1 Question 3: Age of the patient (N=203)

Table 5.2 shows the ages of the patients who experienced an adverse event resulting in malpractice litigation ranged from 1 year to 70-years, the majority (77%) being between 16- 35 years old of which n=156 (77%) were female. Of the remainder; n=45 (22%) were in the age group 36-70 years and 2 in the 1-15 age group. No statistical significance was identified when the Pearson Chi square test was applied.

Table 5.2: Age of the patient: (N =203)

Age	ECP	GP	Total
1-15 years	n=2 (2%)	n=0 (0.0%)	n=2 (0.9%)
16-35 years	n=73 (69.5%)	n=83 (84.7%	n=156 (76 .8 %)
36-70 years	n=30 (28.6%)	n=15 (15.31%)	n=45 (22.2%)
	n=105 (100.0%)	**n=98 (100.0%)**	**N=203 (100.0%)**

5.3.2.2 Question 4: Gender (N=203)

Table 5.3 shows that the majority of patients n=175 (86.2%) in the study were female with n=28 (13.8%) being male.

A significant difference (p=0.01) was identified between Gauteng and Eastern Cape provinces concerning gender by applying the Pearson Chi-square statistical test.

Table 5.3: Gender (N=203)

Gender	ECP	GP	Total
Female	n=85 (81.0 %)	n=90 (91.8%)	n=175 (86.2%).
Male	n=20 (19.0 %)	n=8 (8.2%)	n=28 (13.8%)
Total	**n=105 (100.0%)**	**n=98 (100.0%)**	**N=203 (100.0%)**

5.3.2.3 Question 5: Marital Status (N=203)

As shown in table 5.4, the majority of the patients, n=140 (69.1%), were single, followed by married n=53 (26.1%). There was no statistically significant difference between the ECP and GP provinces concerning marital status when applying the Pearson Chi-square test (p=0.131).

Table 5.4: Marital status (N=203)

Marital status	ECP	GP	Total
Single	n=75 (71.4%)	n=65 (66.3 %)	n=140 (69.1 %)
Married	n=25 (23.8%)	n=28 (28.6%)	n=53 (26.1%)
Partner	n=0 (0.0%)	n=2 (2.0%)	n=2 (1.0%)
Widow/Widower	n=3 (2.9%)	n=1 (1.0%)	n=4 (2.0%)
Divorced	n=2 (1.9%)	n=2 (2.0)	n=4 (2.0%)
Total	**n=105 (100.0%)**	**n=98 (100.0%)**	**N=203 (100.0%)**

5.3.2.4 Question 6: Dependents (N=203)

The majority of patients had no dependents, n=121 (59.6%), followed by patients who had one dependent n=39 (19.2%). The Pearson Chi-square statistical test revealed a significant difference (p=0.01) between Gauteng and the Eastern Cape Province concerning the number of dependents.

Table 5.5: Dependents (N=203).

Dependents	ECP	GP	Total
None	n=62 (59.0 %)	n=59 (60.2%)	n=121 (59.6%)
One	n=10 (9.5%)	n=29 (29.6%)	n=39 (19.2%)
Two	n=6 (5.7%)	n=1 (1.0%)	n=7 (3.4%)
Three	n=0 (0.0%)	n=4 (4.1%)	n=4 (2.0%)
>Three	n=0 (0.0%)	n=1 (1.0%)	n=1 (0.5)
Not documented	n=25 (24.0%)	n=4 (4.1%)	n=29 (14.3%)
99 (Child/neonate)	n=2 (2.0%)	n=0 (0.0%)	n=2 (1.0%)
Total	**n=105 (100.0%)**	**n=98 (100.0%)**	**N=203 (100.0%)**

5.3.2.5 Question 7: Disability on admission (N=203)

Table 5. 6 shows that n=193 (95.1%) patients had no disability on admission, and n=10 (4.9%) had a disability.

Applying the Pearson Chi-square statistical test, there was no statistically significant difference (p=0.148) between Gauteng and the Eastern Cape Province regarding disability on admission.

Table 5.6: Disability on admission (N=203)

Disability	ECP	GP	Total
Yes	n=3 (2.9%)	n=7 (7.1%)	n=10(4.9 %)
No	n=102 (97.1%)	n=91 (92.9%)	n=193 (95.1 %)
Total	**n=105 (100.0 %)**	**n=98 (100.0%)**	**N=203 (100%**

5.3.2.6 Question 8: Social habits (Smoking, Unsolicited drugs, Alcohol) (N=203).

In this question, n=147 (72.4%) of responses were not documented, as shown in table 5.7.

The Pearson Chi-square test revealed a statistically significant difference (p=0.01) between Gauteng and the Eastern Cape public healthcare sectors concerning social habits whether patients smoked, used alcohol or use unsolicited drugs.

In the Eastern Cape public healthcare sector, nursing staff were more likely not to document whether the patients smoked, used alcohol or use unsolicited drugs or not.

Table 5.7: Social habits (N=203)

	ECP	GP	Total
Smoking			
Yes	n=0 (0.0%	n=10 (10.2 %)	n=10 (4.9 %)
No	n=11 (10.5%)	n=30 (30.6%)	n=41 (20.2%)
Not documented	n=91 (86.7%)	n=56 (57.1%)	n=147 (72.4%)
99 (Not applicable)	n=3 (2.9%)	n=2 (2.0%)	n=5 (2.5%)
Total	**n=105 (100%)**	**n=98 (100.0%)**	**N=203 (100.0%)**
Unsolicited drugs			
Yes	n=0 (0.0%	n=4 (4.1%)	n=4 (2.0) %
No	n=11 (10.5%)	n=22 (22.4%)	n=33 (17.6%)
Not documented	n=91 (86.7%)	n=70 (71.4%)	n=161 (79.3%)
99 (not applicable)	n=3 (3.0%)	n=2 (2.0%)	n=5 (2.5%)
Total	**n=105 (100.0%)**	**n=98 (100.0%)**	**N=203 (100.0%)**
	ECP	**GP**	**Total**
Alcohol			
Yes	n=0 (0.0%)	n=10 (10.2%)	n=10 (4.9 %)
No	n=10 (10.0 %)	n=30 (30.6%)	n=40 (19.7 %)
Not documented	n=92 (88.0%)	n=56 (57.1%)	n=148 (72.9%)
99 (not applicable)	n=3 (2.8%)	n=2 (2.0%)	n=5 (2.5 %)
Total	**n=105 (100%)**	**n=96 (100%)**	**N=203 (100.0%)**

5.3.2.7 Question 9: Underlying medical condition on admission, e.g. hypertension (N=203)

Table 5.8 shows that n=141 (69.5%) of the patients did not have any medical condition on admission while n=55 (27.1 %) had a medical condition.

A significant statistical difference was identified between the Gauteng and EC healthcare sector about patients who had preexisting medical conditions on admission when the Pearson Chi-square (p=0.02) statistical test was applied.

Table 5.8: Medical condition on admission e.g. hypertension (N=203)

	ECP	GP	Total
Medical condition on admission			
Yes	n=19 (18.1%)	n=36 (36.7%)	n=55 (27.1%)
No	n=83 (79.0%)	n=58 (59.2%)	n=141 (69.5%)
Not Documented	n=3 (2.9%)	n=4 (4.1%)	n=7 (3.4%)
Total	**n=105 (100.0 %)**	**n=98 (100.0%)**	**N=203 (100.0%)**

5.3.2.8 Question 10: Employment at the time of admission (N=203)

Majority of patients n=168 (82.8%) were not employed at the time of admission, as shown in Table 5.9. No statistically significant difference (p=0.238) concerning the employment status of patients at the time of admission between Gauteng and EC provinces as revealed by the Pearson Chi-square test was applied.

Patients from both provinces had equally high unemployment rates.

Table 5.9: Employment (N=203)

	ECP	GP	Total
Employment			
Employed	n=11(10.5%)	n=10 (10.2%)	n=21(10.3%)
Self Employed	n=2 (1.9%)	n=6 (6.1%)	n=8(3.9%)
Not Employed	n=89 (84.8%)	n=79 (80.6%)	n=168 (82.8%)
Pensioner	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5%)
NA (child)	n=2 (1.9%)	n=3 (3.1 %)	n=5 (2.5%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0%)**

5.3.2.9 Question 11: Type of Employment at the time of admission (N=203)

Only n=29 (14.3%) of the patients on admission were employed, of which n=17(8.5%) are labourers or unskilled, as shown in table 5.10. No significant difference was identified between Gauteng and EC provinces with reference to the type of employment at the time of admission as shown when the Pearson Chi-square test was applied (p=0.660).

Table 5.10: Type of employment at the time of admission (N=203)

	ECP	GP	Total
Type of Employment			
Professional	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Technical	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5%)
Business	n=2 (1.9%)	n=3 (3.1%)	n=5 (2.5%)
Administrative	n=2 (1.9%)	n=4 (4.1%)	n=6 (3.0 %)
Tradesman	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0%)
Labourers/unskilled	n=10(9.5%)	n=7 (7.1%)	n=17 (8.5%)
Other	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0%)
99 (not applicable)	n=90(85.7%)	n=84 (85.7%)	n=174 (85.7%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203(100.0 %)**

5.3.3 Section C: Hospitalisation (Questions 12-16)

In this section, hospitalisation refers to the admission type, diagnosis, care delivered and diagnostic tests done.

5.3.3.1 Question 12: Availability of ward notes for auditing (N=203)

Table 5.11 shows that the nursing ward notes were all available for auditing, n=203 (100%).

Table 5.11: Availability of the nursing ward notes (N=203)

	ECP	GP	Total
Availability of the nursing ward notes			
Yes	n=105(100%)	n=98 (100%)	n=203 (100%)
No	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.2 Question 13: Completeness of the nursing process documents (N=203)

Table 5.12 shows that the majority of the trial bundles, n=128 (63.1%) audited, had an incomplete set of nursing process documents, only n=75 (36.9%) were complete.

A statistically significant difference (p=0.01) was identified between the Gauteng and EC provinces concerning the completeness of the nursing process documents when the Pearson Chi-square statistical test was applied.

The Eastern Cape public healthcare was more likely to have incomplete sets of nursing process documents.

Table 5.12: Completeness of the nursing ward notes (N=203)

	ECP	GP	Total
Completeness of the nursing ward notes			
Complete	n=25 (23.8%)	n=50 (51.0%)	n=75 (36.9 %)
Incomplete	n=80 (76.2%)	n=48 (49.0%)	n=128(63.1%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0)**

5.3.3.3 Question 14: Reasons for admission (N=203)

Table 5.13 shows that the majority of patients n=136 (67.0 %) were admitted for emergency conditions. There was no statistically significant difference between Gauteng and EC provinces concerning the reasons for admission when applying the Pearson Chi-square test (p=0.127).

Table 5.13: Reason for admission (N=203)

	ECP	GP	Total
Reasons for admission			
Elective surgery	n=5 (4.8%)	n=3 (3.1%)	n=8 (3.9%)
Planned treatment	n=2 (1.9%)	n=1 (1.0%)	n=3 (1.5 %)
Emergency	n=73 (69.5%)	n=63 (64.3%)	n=136 (67.0 %)
Ill/Sick	n=13 (12.4%)	n=5 (5.1%)	n=18 (8.9 %)
Other	n=12 (11.4%)	n=26 (26.5%)	n=38 (18.7 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0) %**

5.3.3.4 Question 15: Discipline to which the patient was admitted before the adverse event (N=203)

The major discipline in which adverse events occurred were midwifery and obstetrics, n=149 (73.4%), as shown in table 5.14.

A statistically significant difference (p=0.01) was found between Gauteng and ECP concerning the discipline to which the patients were admitted applying the Pearson Chi test. Gauteng was more likely to admit patents to midwifery/ obstetrics.

Table 5.14: Discipline (N=203)

	ECP	GP	Total
Discipline			
Cardiology	n=0 (0.0%)	n= (0.0%)	n=0 (0.0 %)
Gynaecology	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5 %)
Medical	n=16 (15.2%)	n=5(5.1%)	n=21(10.3%)

Midwifery and obstetrics	n=57 (54.3%)	n=92 (93.9%)	n=149(73.4%)
Neonatology	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5 %)
Nephrology	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.00 %)
Neurosurgery	n=0 (0.0%)	n=1 (1.0%)	n=1 (0.5 %)
Neurology	n=0 (0.0%)	n= 0 (0.0%)	n=0 (0.0%)
Orthopaedics	n=6 (5.7%)	n=0 (0.0%)	n=6 (3.0 %)
Ophthalmology	n=1 (1.0%)	n=0(0.0%)	n=1 (0.5 %)
Paediatrics	n=2 (1.9%)	n=0 (0.0%)	n=2 (1.0%)
Psychiatry	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Trauma	n=18 (15.2%)	n=0(0.0%)	n=18 (8.9 %)
General Surgery	n=3 (2.9%)	n=0 (0.0%)	n=3 (1.5 %)
Cardiac Surgery	n=0 (0.0%)	n=0 (0.0%)	n=0 (0. 0 %)
Other	n=0 (0.0%)	n=0(0.0%)	n=0 (0.0%)
Total	**n=105 (100.0 %)**	**n=98 (100.0%)**	**N=203 (100.0 %)**

5.3.3.5 Question 16: Type of ward/unit to which the patient was admitted before the adverse event occurred (N=203)

Most patients were admitted to the labour ward n=143 (70.4%), followed by emergency/casualty n=30 (14.8%), as shown in table 5.15.

Applying the Pearson Chi-square statistical test, a significant difference (p=0.01) was found between the Gauteng and Eastern Cape provinces with regard to the units where the patients were admitted before the adverse event occurred. The Gauteng public healthcare sector was more likely to have patients admitted to the labour ward before the adverse event.

Table 5.15: Type of wards (N=203)

	ECP	GP	Total
Type of wards/units			
Emergency/Casualty	n=22 (21.0)	n=8 (8.2%)	n=30 (14.8%)
General ward	n=15 (14.3%)	n=4 (4.1%)	n=19 (9.4%)
Pediatrics	n=3 (%)	n=1 (1.0%)	n=4 (2.0%)
ICU	n=1 (1.0 %)	n=0 (0.0%)	n=1 (0.5%)
Antenatal Ward	n=4 (3.8%)	n=0(0.0%)	n=4 (2.0%)
Labour	n=58 (55.2%)	n=85(86.7%)	n=143 (70.4%)
Neonatology	n=0(0.0%)	n=0(0.0%)	n=0(0.0%)
Postnatal ward	n=2 (1.9%)	n=0. (0.0%)	n=2 (0.9%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100%)**

5.3.3.6 The nursing process (questions 17 to 31)

5.3.3.6.1 Question 17: Status of the initial assessment (N=203)

Table 5.16 indicates that n=148 (72.9%) of the initial assessments were incomplete, n=52 (25.6%) were complete and n=3 (1.5%) were not done. A statistically significant difference (p=0.004) was identified about the level of completeness of the initial assessment between Gauteng and EC provinces. Eastern Cape public healthcare sector was more likely to have incomplete initial assessments.

Table 5.16: Status of the Initial assessments

	ECP	GP	Total
Status of the Initial assessments			
Complete	n=18 (17.1%)	n=34 (34.7%)	n=52 (25.6 %)
Incomplete	n=86 (81.9%)	n=62 (63.3%)	n=148 (72.9 %)
Not Done	n=1 (1.0%)	n=2 (2.0%)	n=3 (1.5 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0)**

5.3.3.6.2 Question 18: Status of the care plan (N=203)

As shown in table 5.17 the majority of care plans n=144 (70.9%) were incomplete, only n= 44 (21.7%) were complete and n=15 (7.4%) were not done.

A statistically significant difference (p=0.005) was identified between the Gauteng and Eastern Cape provinces about the status of the care plan as shown by the Pearson Chi-square test. The Eastern Cape public healthcare sector is more likely to have incomplete care plans. The Eastern Cape public healthcare sector is more likely to have incomplete care plans.

Table 5.17: Status of the care plan (N=203)

	ECP	GP	Total
Status of the care plan			
Complete	n=15 (14.3%)	n=29 (29.6%)	n=44 (21.7%)
Incomplete	n= 82 (78.1%)	n=62 (63.3%)	n=144 (70.9 %)
No done	n=8 (7.6%)	n=7 (7.1%)	n=15 (7.4 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0)**

5.3.3.6.3 Question 19: Implementation of the care plan (N=203)

As illustrated in table 5.18, n=161 (79.3%) of the care plans were implemented, compared to n=42 (20.6%) not implemented. A statistically significant difference (p=0.01) was identified between Gauteng and EC provinces concerning the implementation of care plans as shown by the Pearson Chi-square test with the Gauteng public healthcare sector being more likely to implement nursing care plans.

Table 5.18: Implementation of care plans (N=203)

	ECP	GP	Total
Implementation of care plans			
Yes	n=65 (61.9%)	n=96 (98.0%)	n=161 (79.3 %)
No	n=40 (38.1%)	n=2 (2.0%)	n=42 (20.6 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.4 Question 20: Special care plans required (N=203)

Table 5.19 shows that the majority of study patients n=187 (92.1%) required special care plans. The Pearson Chi-square statistical test revealed a significant difference (p=0.003) between the Gauteng and Eastern Cape provinces with regard to patients concerning special care plans.

Table 5.19: Special care plans required (N=203)

	ECP	GP	Total
Special Care plans required			
Yes	n=94(89.5%)	n=93(94.9%)	n=187 (92.1 %)
No	n=11 (10.5%)	n=5 (5.1%)	n=16 (7.9)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0)**

5.3.3.6.5 Question 21: Status of the special care plan (N=203)

Table 5.20 shows that the majority of the special care plans were incomplete n=139 (68.5%), and n=13 (6.4%) had no special care plans formulated.

A statistically significant difference (p=0.001) was identified between the Gauteng and EC provinces concerning the status of the special care plans, as shown by the Pearson Chi-square test. Gauteng Province public healthcare sector was more likely to have complete special care plans.

Gauteng Province public healthcare sector was more likely to have complete special care plans.

Table 5.20: Status of the special care plan (N=203)

	ECP	GP	Total
Status of the care plan			
Complete	n=14 (13.3%)	n=21 (21.4%)	n=35 (17.2 %)
Incomplete	n=71 (67.6%)	n=68 (69.4%)	n=139 (68.5 %)
Not done	n=9 (8.6%)	n=4 (4.1%	n=13 (6.4 %)
99 (not applicable)	n=11(10.5%)	n=5 (5.1%)	n=16 (7.8 %)
Total	**n=105 (100%)**	**n=98 (100%**	**N=203 (100.0 %)**

5.3.3.6.6 Question 22: Implementation of special care plans (N=203)

Table 5.21 shows that n=141 (69.5%) special care plans were implemented and n=46 (22.7%) were not implemented.

A statistically significant difference (p=0.002) was found between the Gauteng and EC provinces concerning the implementation of special care plans, as shown by the Pearson Chi-square test. Gauteng public healthcare sector was more likely to have special care plans that were implemented.

Table 5.21: Special care plans implemented (N=203)

	ECP	GP	Total
Special care plans implemented			
Yes	n=57 (54.3%)	n=84 (85.7%)	n=141 (69.5 %)
No	n=37 (35.2%)	n=9 (9.2%)	n=46 (22.7 %)
99 (not applicable)	n=11 (10.4%)	n=5 (5.1%)	n=16 (7.9%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7 Question 23: Vital signs monitored (N=203)

In this question, the results about how the vital signs were monitored are presented in sub-questions as shown in table 5.22

5.3.3.6.7.1 Blood pressure monitored (N=203)

The blood pressure was monitored incompletely n=161 (79.3%), as shown in table 5.22.

There was no statistically significant difference between Gauteng and EC provinces concerning blood pressure monitoring when applying the Pearson Chi-square test (p=0.962).

Table 5.22: Blood pressure monitored (N=203)

	ECP	GP	Total
Blood pressure			
Complete	n=20 (19.0%)	n=22(22.4%)	n=42 (20.7 %)
Incomplete	n=85(81.0%)	n=76 (77.6%)	n=161 (79.3 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.2 Pulse monitoring (N=203)

Table 5.23 shows that n=160 (78.8%) patients' pulse were monitored incompletely with no significant difference between the provinces, as shown by the Pearson Chi-Square test (p=0.569).

Table 5.23: Pulse monitored (N=203)

	ECP	GP	Total
Pulse			
Complete	n=20 (19.0%)	n=22 (22.4%)	n=42 (20.7 %)
Incomplete	n=85 (81.0%)	n=75 (76.5%)	n=160 (78.8 %)
Not Done	n=0 (0.0%)	n=1 (1.1%)	n=1 (0.4 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.3 Foot pulse monitoring (N=203)

Table 5.24 shows that 15 patients required foot pulse monitoring, of which n=4(2.0%) were incompletely done. A statistically significant difference (p=0.048) was identified between Gauteng and Eastern Cape provinces about foot pulse monitoring as shown by the Pearson Chi-Square test.

Table 5.24: Foot pulse monitored (N=203)

	ECP	GP	Total
Foot pulse			
Complete	n=4 (3.8%)	n=1 (1.0%)	n=5 (2.5 %)
Incomplete	n=4 (3.8%)	n=0 (0.0%)	n=4 (2.0 %)
Not Done	n=5 (4.8%)	n=1 (1.0%)	n=6 (3.0 %)
99 (not applicable)	n=92 (87.6%)	n=96 (98%)	n=188 (92.6 %)
Total	**n=105 (100%)**	**n=96 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.4 Foetal heart monitoring (N=203)

The research results show that n=154 patients required foetal heart monitoring, but only n=10(4.9%) were monitored completely, and n=143(70.4%) were monitored incompletely.

A statistically significant difference (p=0.01) was shown between the Gauteng and the Eastern Cape Province public healthcare sectors concerning foetal heart monitoring as shown by the Pearson square test. The Eastern Cape Province public healthcare sector was more likely to monitor the foetal heart of patients incompletely.

Table 5.25: Foetal heart monitored (N=203)

	ECP	GP	Total
Foetal heart monitored			
Complete	n=6 (5.7%)	n=4 (4.1%)	n=10 (4.9%)
Incomplete	n=58 (55.2%)	n=85 (86.7%)	n=143 (70.4%)
Not Done	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5%)
99 (not applicable)	n=40 (38.1%)	n=9 (9.2%)	n=49 (24.1 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.5 Respiration monitoring (N=203)

Table 5.26 showed that respiration n=156 (76.8 %) were incompletely monitored in this study, and n=43 (21.2 %) were monitored completely. No statistically significant difference (p=0.322) as applied by the Pearson Chi Square test was shown between the Gauteng and Eastern Cape public healthcare sectors with regards to respiratory rate monitoring.

Table 5.26: Respirations monitored (N=203)

	ECP	GP	Total
Respirations monitored			
Complete	n=22 (21.0%)	n=21(21.4%)	n=43 (21.2 %)
Incomplete	n=81 (77.1%)	n=75 (76.5%)	n=156 (76.8 %)
Not Done	n=2 (1.9%)	n=2 (2.0%)	n=4 (2.0 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**n=203 (100 %)**

5.3.3.6.7.6 Temperature monitoring (N=203)

Table 5.27 shows that the temperature n=160 (78.8%) of the patients were incompletely monitored. No statistically significant statistical differences were identified between the provinces, (p=0.070).

Table 5.27: Temperature monitored (N=203)

	ECP	GP	Total
Temperature monitored			
Complete	n=19 (18.1%)	n=18 (18.4%)	n=37 (18.2 %)
Incomplete	n=86 (81.9%)	n=74(75.5%)	n=160 (78.8 %)
Not Done	n=0 (0.0%)	n=6 (6.1%)	n=6 (2.9 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100 %)**

5.3.3.6.7.7 Monitoring intake and output (N=203)

The study shows that of n=121 patients that required intake and output monitoring only n=20 (9.9%) were monitored completely with n=88 (43.3%) monitored incompletely, and n=13 (6.4%) not monitored at all. A statistically significant difference was shown between the Gauteng and Eastern Cape province public healthcare sector concerning monitoring of intake and output, as shown by the Pearson Chi-square test (p=0.01).

Table 5.28: Intake and output monitored (N=203)

	ECP	GP	Total
Intake and output monitored			
Complete	n=14 (13.3%)	n=6 (6.1%)	n=20 (9.9 %)
Incomplete	n=66 (62.9%)	n=22 (22.4%)	n=88 (43.3 %)
Not Done	n=10 (9.5%)	n=3 (3.1%)	n=13 (6.4 %)
99 (not applicable)	n=15 (14.3%)	n=67 (68.4%)	n=82 (40.4%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.8 Weight monitoring (N=203)

Table 5.29 shows that n=174 patients required weight monitoring, of which n=25 (12.3%) were monitored incompletely and n=7 (3.4%) were not monitored.

Applying the Pearson Chi-Square test, a significant statistical difference was identified (p=0.01) between the provinces ECP and GP concerning monitoring the weight of patients.

The Eastern Cape Province public healthcare sector was more likely to monitor the weight of patients incompletely.

Table 5.29: Weight monitored (N=203)

	ECP	GP	Total
Weight monitored			
Complete	n=75 (71.4%)	n=67 (68.4%)	n=142 (70.0 %)
Incomplete	n=24 (22.9%)	n=1 (1.0%)	n=25 (12.3 %)
Not Done	n=5 (4.8%)	n=2 (2.0%)	n=7 (3.4 %)
99 (not applicable)	n=1 (1.0%)	n=28 (28.6%)	n=29 (14.3 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.9 Neurological observations (N=203)

Table 5.30 shows that n=18 patients required neurological observation monitoring, n=5 (2.5%) were monitored incompletely, and n=8 (3.9) were not monitored.

A Pearson Chi-Square test was applied, and a significant statistical difference was identified (p=0.055) between Gauteng and Eastern Cape public healthcare sectors concerning the monitoring of neurological observations of patients.

Table 5.30: Neurological Observations (N=203)

	ECP	GP	Total
Neurological Observations monitored			
Complete	n=5 (4.8%)	n=0 (0.0%)	n=5 (2.5%)
Incomplete	n=4 (3.8%)	n=1 (1.0%)	n=5 (2.5%)
Not Done	n=6 (5.7%)	n=2 (2.0 %)	n=8 (3.9%)
99 (not applicable)	n=90 (85.7%)	n=95 (96.9%)	n=185 (91.1 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.10 Post spinal surgery observations (N=203)

Sixteen patients required post spinal surgery observations. Nine (4.4%) were monitored completely, and n=7 (3.4%) were not monitored.

A Pearson Chi-square test was applied, and no statistically significant difference (p=0.087) was identified between Gauteng and Eastern Cape Province public healthcare sectors concerning the post spinal surgery observations of patients.

Table 5.31: Post spinal surgery observations (N=203)

	ECP	GP	Total
Complete	n=8 (7.6%)	n=1 (1.0%)	n=9 (4.4 %)
Incomplete	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Not Done	n=1 (1.0%)	n=6 (6.1%)	n=7 (3.4 %)
99 (not applicable)	n=96 (91.4%)	n=91 (92.9%)	n=187 (92.1%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.11 Mental status observations

Table 5.32 shows that n=109 patients required mental status observations, of which n=97 (47.8%) were monitored completely, n= 6 (3.0%) were monitored incompletely and n=6 (3.0%) were not monitored.

A Pearson Chi-square test was applied, and a statistically significant difference was identified (p=0.01) between Gauteng and Eastern Cape Province public healthcare sectors concerning the mental status observations of the patients.

The Eastern Cape public healthcare sector was more likely to complete observations of a patient's mental status.

Table 5.32: Mental status observations (N=203)

	ECP	GP	Total
Metal status observations			
Complete	n=57 (54.3%)	n=40 (40.8%)	n=97 (47.8 %)
Incomplete	n=2 (1.9%)	n=4 (4.1%)	n=6 (3.0 %)
Not Done	n=5 (4.8%)	n=1 (1.0%)	n=6 (3.0 %)
99 (not applicable)	n=41 (39.0%)	n=53 (54.1%)	n=94 (46.3 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.7.12 Continuous ECG monitoring

Six patients required continuous ECG monitoring in this study, n=2(1%) were monitored incompletely, and n=4(2%) were not monitored this is shown in table 53.

A Pearson Chi-square test was applied, and no statistically significant difference (p=0.092) was identified between Gauteng and Eastern Cape Province public healthcare sectors concerning the ECG monitoring.

Table 5.33: Continuous ECG monitoring (N=203)

	ECP	GP	Total
Continues ECG monitoring			
Complete	n= (0.0%)	n=0(0.0%)	n=0 (0.0 %)
Incomplete	n=1 (1.0%)	n=1 (1.1.0%)	n=2 (1.0 %)
Not Done	n=1 (1.0%)	n=3 (3.1%)	n=4 (2.0 %)
99 (not applicable)	n=103 (98.1%)	n=94 (95.9%)	n=197 (97.0 %)
Total	**n=105 (100%)**	**n=98 9100%)**	**N=203 (100.0 %)**

5.3.3.6.7.13 Continuous oxygen monitoring

Eight patients required continuous oxygen monitoring in this study, n=2(1%) were monitored completely, and n= 4(2%) were not monitored. This is shown in table 5.34.

A Pearson Chi-square test was applied, and no statistically significant difference (p=0.092) was identified between Gauteng and Eastern Cape Province public healthcare sectors concerning oxygen monitoring.

Table 5.34: Continuous oxygen monitoring (N=203)

	ECP	GP	Total
Continues Oxygen monitoring			
Complete	n=1 (1.0%)	n=1 (1.0%)	n=2 (1.0 %)
Incomplete	n=1 (1.0%)	n=1 (1.0%)	n=2 (1. 0 %)
Not Done	n= 3 (2.9%))	n=1 (1.0%)	n=4 (2.0 %)
99 (not applicable)	n=101 (96.2%)	n=95 (96.9)	n=195 (96.1 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.8 Question 24: Tests carried out pre-adverse events

Table 5.35 shows that most patients who required tests were not done, haemoglucotest n=141 (71.2%), blood gases n=110 (74.3%), urea and electrolytes n=95 (58.6 %).

In summary; a statistically significant difference (p=0.01) was identified when a Pearson Chi-square test was applied between the Gauteng and Eastern Cape Province public healthcare sectors concerning tests before the adverse events specifically with haemoglucotest (p=0.01), blood gasses (p=0.01) and urea and electrolytes (p=0.01). Eastern Cape was more likely to do the tests.

Table 5.35: Tests carried out pre-adverse events

	Done			Not Done		
Tests	**ECP**	**GP**	**Total**	**ECP**	**GP**	**Total**
Haemoglucotest (N=198)	n=45 (96.5%)	n=12 (21.1%)	n=57 (28.8%)	n=63 (44.7%)	n=78 (39.4%)	n=141 (71.2%)
Haemoglobin (N=193)	n=83 (50.1%)	n=80 (49.8%)	n=163 (84.5%)	n=14 (46.7 %)	n=16 (53.3%)	n=30 (15.5%)
Urine tests (N=202)	n=102 (53.7%)	n=88 (43.6%)	n=190 (94.1 %)	n=4 (33.3%)	n=8 (66.7 %)	n=12 (5.9%)
Urea and electrolytes (N=162)	n=53 (32.7 %)	n=14 (8.6%)	n=67 (41.4%)	n=46 (27.5%)	n=49 (29.3%)	n=95 (58.6%)
Blood gases (N=148)	n=31 (81.6%)	n=7 (18.4%)	n=38 (25.7%)	n=63 (57.3%)	n=47 (42.8%)	n=110 (74.3)
Full blood count (N=162)	n=51 (74.0%)	n=18 (26.1%)	n=69 (34.0%)	n=47 (50.5%)	n=46 (49.5%)	n=93 (45.8%)
Liver functions s (N=116)	n=18 (100%)	n=0 (0.0%)	n=18 (9.0%)	n=52 (56.0%)	n=41 (44.1%)	n=93 (46.3%)
Others (N=4)	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0%)	n=1 (25%)	n=3 (75%)	n=4 (2.0%)
n=1185 (100%)	n=383 (63.6%)	n=219 (36.4%)	n=602 (50.8%)	n=290 (50.2%)	n=288 (49.8 %)	n=578 (38.4%)

5.3.3.6.9 Question 25: Test results interpreted (N=203)

As shown in table 5.36, n=138 (68.0 %) of the study's patient test results were correctly interpreted, n=46 (22.7 %) of these results were incorrectly interpreted, and n=19 (9.4%) were not interpreted by the registered nurse.

A statistically significant difference (p=0.003) was identified by applying the Pearson Chi-square test between the Eastern Cape and Gauteng public healthcare sector concerning the interpretation of diagnostic tests.

Table 5.36: Tests results interpreted (N=203)

	ECP	**GP**	**Total**
Results interpreted			
Correctly interpreted	n=60 (57.1%)	n=78 (79.6%)	n=138 (68.0 %)
Incorrectly interpreted	n=26 (24.8%)	n=20 (20.4%)	n=46 (22.7 %)
Not interpreted	n=19 (18.1%)	n=0 (0.0%)	N=19 (9.4 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**n=203 (100.0 %)**

5.3.3.6.10 Question 26: Patients' results reported to the doctor (N=203)

The majority n=167 (82.3 %) of the patients' diagnostic tests, were reported, and n=36 (17.7%) were not reported to the doctor. This is shown in table 5.37.

No statistical significance (p=0.207) was identified between the Eastern Cape and Gauteng public healthcare sectors concerning reporting patients' results to the doctor.

Table 5.37: Test results reported to the doctor (N=203)

	ECP	GP	Total
Results reported to the doctor			
Yes	n=85 (80.1%)	n=82 (83.7%)	n=167 (82.3 %)
No	n=20 (19.4%)	n=16 (16.3%)	n=36 (17.7 %)
Total	**n=105 (100%)**	**n=8 (100%)**	**N=203 (100.0 %)**

5.3.3.6.11 Question 27: Action taken based on the diagnostic results (N=203)

Table 5.38 shows that 133 (65.5%) study patients had actions taken based on their diagnostic results while there was no action taken on the diagnostic results of 65 (32.0%) study patients. No statistical significance (p=0.631) was identified between Eastern Cape and Gauteng public healthcare sectors concerning action taken based on the diagnostic results.

Table 5.38: Action taken based on the diagnostic test results (N=203)

	ECP	GP	Total
Action is taken based on the diagnostic test results			
Yes	n=68 (64.8%)	n=65 (66.3%)	n=133 (65.5 %)
No	n=35 (33.3%)	n=30 (30.6%)	n=65 (32.0 %)
99 (not applicable)	n=2 (1.9%)	n=3 (3.1%)	n=5 (2.5 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.12 Question 28: Preoperative assessment for surgery (N=203)

Table 5.39 shows, the preoperative assessments of n=101 (49.8%) study patients requiring preoperative assessments were not done, and n=22 (10.8%) were incompletely done. No, statistically significant difference was found (p=0.625%) when the Pearson Chi-square test was applied between Gauteng and Eastern Cape Province concerning preoperative assessment for surgery.

Table 5.39: Pre-operative assessment (N=203)

	ECP	GP	Total
Pre-operative assessment			
Complete	n=14 (13.3%)	n=11 (11.2%)	n=25 (12.3 %)
Incomplete	n=13 (12.4%)	n=9 (9.2%)	n=22 (10.8 %)
Not Done	n=55 (52.4%)	n=46 (46.9%)	n=101 (49.8 %)
99 (not applicable)	n=23 (21.9%)	n=32 (32.7%)	n=55 (27.1 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.13 Question 29: Treatment/technique/management given as prescribed (N=203)

Table 5.40 shows that n=70 (34.5%) of the treatment or technique or management required by study patients was given as prescribed, while n=130 (64.0%) was not.

A statistically significant difference (p=0.018) between the Eastern Cape and Gauteng public healthcare sector was identified concerning treatment/technique/ management given as prescribed by applying the Pearson Chi-square test.

ECP is more likely not to give treatment or technique or management as prescribed.

Table 5.40: Treatment /technique/management given as prescribed (N=203)

	ECP	GP	Total
Treatment given as prescribed			
Yes	n=29 (27.6%)	n=41 (41.8%)	n=70 (34.5%)
No	n=76 (72.4%)	n=54 (55.1%)	n=130 (64.0 %)
99 (not applicable)	n=0 (0.0%)	n=3 (3.1%)	n=3 (1.5 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.3.6.14 Question 30: Patient's reports (initial, progress, interim and discharge reports)

Most reports as shown in table 5.41 were incomplete namely initial reports n=133 (65.5%), progress reports n=169 (83.3%), correct interpretation of clinical manifestation reports were incomplete n=163 (80.3%), interim reports n=169 (83.3%) and reports indicating if the doctor was contacted or not were incomplete n=153 (75.4%). In n=102 (50.2%) trial bundles no discharge reports were written about the patients. A statistically significant difference (p=0.004) was identified between the Eastern Cape and Gauteng public healthcare sectors regarding the patient's reports when a Pearson Chi-square test was applied.

Eastern Cape Province was more likely to have incomplete initial reports.

Table 5.41: Patient's reports (initial, progress, interim and discharge reports)

Patients Reports	ECP	GP	Total
Initial reports			
Complete	n=25 (23.8%)	n=40 (40.8%)	n=65 (32.0 %)
Incomplete	n=77 (73.3%)	n=56 (57.1%)	n=133 (65.5 %)
Not done	n=3 (2.9 %)	n=2 (2.0%)	n=5 (2.5 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**n=203 (100%**
Progress reports			
Complete	n=9 (8.6%)	n=20 (20.4%)	n=29 (14.3 %)
Incomplete	n=93 (88.6%)	n=76 (77.6%)	n=169 (83.3 %)
Not done	n=3 (2.9%)	n=2 (2.0%)	n=5 (2.5 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100%)**
Patients Reports	**ECP**	**GP**	**Total**
Correct interpretation of clinical manifestations reports			
Complete	n=19 (18.1%)	n=15 (15.3%)	n=34 (16.7 %)
Incomplete	n=81 (77.1%)	n=82 (83.7%)	n=163 (80.3 %)
Not done	n=5 (4.8%)	n=1 (1.0%)	n=6 (3.0 %)
Total	**n=105(100%)**	**n=98 (100%)**	**N=203 (100%)**
Interim reports			
Complete	n=16 (15.2%)	n=13 (13.3 %)	n=29 (14.3 %)
Incomplete	n=85 (81.0%)	n=84(85.7%)	n=169 (83.3%)
Not done	n=4 (3.8%)	n=1 (1.0%)	n=5 (2.5%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100%)**
Report to the doctor reports			
Complete	n=19 (18.1%)	n=15 (15.3%)	n=34 (16.7 %)
Incomplete	n=76 (72.4%)	n=77 (78.6%)	n=153 (75.4 %)
Not done	n=10 (9.5%)	n=6 (6.1%)	n=16 (7.9 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100%)**
Discharge reports			
Complete	n=15 (14.3%)	n=6 (6.1%)	n=21 (10.3 %)
Incomplete	n=45 (42.9%)	n=35 (35.7%)	n=80 (39.4 %)
Not done	n=45 (42.9%)	n=57 (58.2%)	n=102 (50.2 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100%)**

5.3.3.6.15 Question 31: Patient education is given on discharge and death (N=203)

Patients were not given specific health education on discharge, and this includes the families of the patients who died n=158 (77.8%) as illustrated in table 5.42.

No statistically significant differences were identified between the Eastern Cape and Gauteng public healthcare sectors concerning patient education is given on discharge by applying the Pearson Chi-square test (p=0.194).

Table 5.42: Patient Education given on discharge (N=203)

	ECP	GP	Total
Patient education reports			
Yes	n=25 (23.8%)	n=20 (20.4%)	n=45 (22.2%)
No	n=80 (76.2%)	n=78 (79.6%)	n=158 (77.8%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.4 Section D: Operating Room (Question 32)

This section was completed only if the adverse event occurred during surgery.

5.3.4.1 Question 32: Protocols followed in the theatre room (N=67)

Table 5.43 shows that many operating room protocols were not followed.

The study revealed that in n=60(89.6%) cases, the protocol for counting of swabs was implemented.

The study further revealed that the infection control measures required by n=61 (91%) of the n=67 patients requiring these measures did not receive them.

The Pearson Chi-square statistical test revealed a significant difference (p=0.003) between the swab counting protocol, infection control (p=0.004) and use of diathermia (p=0.003) in operating rooms used by the Eastern Cape compared to the Gauteng Province, and that the ECP was more likely not to adhere to protocols in the operating room than in the GP.

Table 5.43: Protocols followed in the theatre room

	Followed (Yes)			Not followed (No)		
Protocols followed in the theatre room	**ECP**	**GP**	**Total**	**ECP**	**GP**	**Total**
Counting Swab (n=67)	n=7 (10.4%)	n=0 (0. %)	**n=7 (10. %)**	n=38 (56.7%)	n=22 (32.8%)	**n=60 (89.6 %)**
Infection control (n=67)	n=6 (9.0%)	n=0 (0. %)	**n=6 (8.9%)**	n=35 (52.2%)	n=26 (38.8%)	**n=61 (91.0%)**
Managing instruments (n=67)	n=7 (10.4%)	n=3 (4.5%)	**n=10 (14.9 %)**	n=38 (56.7%)	n=19 (28.4%)	**n=57 (85.1 %)**
Managing specimens (n=66)	n=5 (7.6%)	n=1 (1.5 %)	**n=6 (9.1%)**	n=40 (60.6%)	n=20 (30.3%)	**n=60 (90.9 %)**
Use of diathermia (n=68)	n=5 (7.3%)	n=0 (0.0%)	**n=5 (2.5%)**	n=40 (58.8%)	n=23 (33.8%)	**n=63 (93.6 %)**
Surgical pause or time out (n=66)	n=5 (7.6%)	n=0 (0.0%)	**n=5 (7.6%)**	n=40 (60.6%)	n=21 (31.8%)	**n=61 (92.4 %)**

5.3.5 Section E: Adverse events (Questions 33-37)

In this section, more than one answer was possible. This section describes the adverse event concerning where the event occurred, and the healthcare professionals involved.

5.3.5.1 Question 33: The environment where the adverse event occurred (N=203)

The majority of the adverse events occurred in the labour ward n=143 (70.4%), followed by casualty trauma n=19 (9.4%), the operating theatre room n=21 (10.3%) and general wards n=7 (3.4%). Out of n=203 patients that had their adverse events, two occurred in the post-natal ward and three occurred in the antenatal ward. Applying the Pearson Chi-square statistical test, a significant difference (p=0.01) was identified between the Eastern Cape and Gauteng public healthcare sectors concerning patients who had an adverse event in the environment where the adverse event occurred.

Gauteng public healthcare sector was more likely to have patients developing an adverse event in the labour ward.

Table 5.44: The environment where the adverse event occurred (N=203)

	ECP	GP	Total
The environment where the adverse event occurred			
General Ward	n=2 (1.9%)	n=5 (5.1%)	n=7 (3.4%)
ICU	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Operating room Theatre	n=18(17.1%)	n=3. (3.0 %)	n=21 (10.3%)
Orthopedic ward	n=3 (2.9%)	n=1(1.0%)	n=4 (2.0 %)
Paediatric Ward	n=3 (2.9%)	n=0 (0.0%)	n=3 (1.5 %)
Neonatology Unit	n=1 (2.9%)	n=0 (0.0%)	n=1 (0.5%)
Casualty/ Trauma	n=15 (14.3%)	n=4(4.1%)	n=19 (9.4%)
Labour	n=58 (55.2%)	n=85(86.7%)	n=143 (70.4%)
Antenatal	n=3(2.9%)	n=0 (0.0%)	n=3 (1.5 %)
Post-natal ward	n=2 (1.9%)	n=0 (0.0%)	n=2 (0.9%)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.5.2 Question 34: Brief description of the adverse event(s)

Due to the sensitivity of the data, only a brief description of the adverse event is given in this section. This is done to ensure the privacy of the court case and the parties involved.

Furthermore, in this study of 203 study patients, a study patient had multiple factors that contributed to an adverse event or more than one adverse event. Poor monitoring, the absence of a doctor, incorrect treatment and failure to respond to clinical manifestations, resulted in the following adverse events: the mother had a fresh stillborn and uterine rupture.

The adverse events are described according to non-obstetric and obstetric and further explanation is given according to the principal type, which contributed to adverse events.

5.3.5.2.1 Midwifery and obstetrics

5.3.5.2.1.1 Labour ward

i Adverse events due to poor monitoring (n=149)

One hundred and forty-three (96.0%) of n=149 adverse events that occurred in the in labour wards due to poor monitoring either of the foetal condition, maternal condition or progress of labour.

Most patients had an uneventful pregnancy, were monitored according to the maternity care guidelines during latent phase of labour but were poorly monitored during the active phase of labour. Poor monitoring of these women during labour resulted in n=135 (94.4%) cerebral palsy births and n=3 fresh stillborn and n=2 women who had uterine rupture.

ii Adverse events due to system failure n=17

Seventeen patients had adverse events in the labour ward either to non-availability of transport, shortage of doctors to perform Caesarian section when it was indicated and shortage of beds in labour wards.

iii Adverse events due to behavioural problems n=7

Seven patients had adverse events because the doctor on call could not be reached, clinical manifestations not responded to and for the reasons that were not stated, although there was a need to take action. Two adverse events were due to patient behavior whereby the patient was uncooperative during labour and the second one did not come to take her Anti-Retroviral treatment (ART) when requested to do so.

iv Incorrect treatment n=18

Eighteen had adverse events due to incorrect treatment, treatment ordered but not given. Some were given treatment that was not ordered, e.g. high doses of oxytocin, misoprostol.

v Lack of Failure to do a swab count n=4: Midwifery department

Four patients had adverse events due to abdominal swabs left inside the abdomen during Caesarian section.

Institutions in the public healthcare sector have a theatre in the labour ward where surgical procedures that are related to maternity conditions are performed.

5.3.5.2.1.2 Ante-natal Ward n=4

Poor monitoring resulted in adverse events that occurred in the antenatal ward resulted in intrauterine death.

5.3.5.2.1.3 Post-natal ward n=2

Adverse events that occurred in the post-natal ward resulted in maternal deaths and n=2 resulted in cerebral palsy. The adverse events occurred due to poor monitoring and failure to take action when needed.

5.3.5.2.2 Non-obstetric adverse events n=60

In this study, n=60 adverse events occurred in other departments excluding midwifery including operating theatre, casualty, general wards, orthopaedic wards and paediatric wards.

5.3.5.2.2.1 Operating room: n=21(35%)

Twenty-one (35.0%) adverse events occurred in the operating theatre room of which n=6 were due to a swab being left inside the abdomen, and n=2 due to a swab being left in the vagina during surgery.

Two adverse events resulted in burns, n=3 resulted in deformity and paralysis, and n=4 occurred due to incorrect surgery and surgery done without the patient's consent.

5.3.5.2.2.2 Trauma/ Casualty n=19 (31.7%)

The adverse events that occurred in the trauma department were due to poor monitoring, poor treatment techniques including not removing a drain when indicated, and failure to remove sutures.

5.3.5.2.2.3 General Ward: n= 7 (11.7%)

Adverse events occurred due to poor monitoring and incorrect medication.

5.3.5.2.2.4 Paediatric ward: n=5 (8.3%)

Adverse events occurred due to poor monitoring of intake and output and drip sites.

5.3.5.2.2.5 Orthopaedic wards: n=4 (6.7%)

Adverse events occurred due to a tight Plaster of Paris that was not monitored properly and treated incorrectly.

5.3.5.3 Question 35: Patient outcome(s) as a result of the adverse event (N=203)

As a result of the adverse event, n=163 (80.3%) patients had their quality of life affected. One hundred and forty-four patients (70.9%) became disabled, n=136 (67.0 %) had an increased

hospital stay, n=4(2.0%) of the patients died as a result of the adverse events, and n=32 (15.8%) had additional surgery as shown in table 5.45.

The Pearson Chi-square statistical test showed significant differences between the Eastern Cape and Gauteng healthcare sectors regarding the outcomes of the adverse events specifically due to disability (p=0.01), death (p=0.01), surgery (p=0.01) and quality of life affected (p=0.01). Patients are more likely to have additional surgery in the ECP and to die as a result of an adverse event which occurred in the ECP while patients are more likely to be disabled from adverse events which occurred in the Gauteng public healthcare sector and more likely to have their quality of life affected.

Table 5.45: The outcomes of the adverse events (N=203)

	ECP	GP	Total
The outcomes of the adverse events			
Additional surgery	n=29 (27.6%)	n=3 (3.1%)	n=32 (15.8 %)
Death	n=4 (3.8%)	n=0 (0.0%)	n=4 (2.0 %)
Disabled	n=58 (55.2%)	n=86 (87.8%)	n=144 (70.9 %)
Increased hospital stay	n=52 (49.5%)	n=84 (85.7%)	n=136 (67.0 %)
Quality of life affected	n=73 (69.5%)	n=90 (91.8%)	n=163 (80.3 %)

5.3.5.4 Question 36: Healthcare professional(s) and non-healthcare professionals responsible for adverse events (N=203).

The responsible healthcare professionals for the adverse events of patients in the study population, included both nursing and medical n=144 (70.9%), n=29 (14.4%) nursing staff and n=15 (7.4%) medical staff only as shown in table 5.46.

There was no statistically significant difference (p=0.160) identified between the Eastern Cape and Gauteng healthcare sectors concerning healthcare professional(s) and non-healthcare professionals responsible for adverse events the when a Pearson Chi-square test was applied.

Table 5.46: Healthcare professional(s) or non-healthcare professionals responsible for adverse events (N=203)

	ECP	GP	Total
Responsible person			
Nursing	n=15 (14.3%)	n=14 (14.3%)	n=29 (14.4 %)
Medical	n=10 (9.5%)	n=5 (5.1%)	n=15 (7.4%)
Both Nursing and Medical	n=71 (67.6%)	n=73 (74.5%)	n=144(70.9 %)
Non-healthcare professional	n=6 (5.7%)	n=1 (1.0%)	n=7 (3.5 %)
Both Nursing and Non-healthcare professional	n=3 (2.9%)	n=3 (3.1%)	n=6 (3.0 %)
Other	n=0 (0.0%)	n=2 (2.0%)	n=2 (1.0 %)
Total	**n=105 (100%)**	**n= 98 (100%)**	**N=203 (100.0 %)**

5.3.5.5 Question 37: Nurse category (ies) involved in the adverse event (N=203)

The study results show that the midwives were mostly involved in the occurrence of adverse events n=149 (84.1%), followed by professional nurses n=22 (12.4%), as shown in table 5.47.

In most adverse events, more than one nurse was involved. Applying the Pearson Chi-square statistical test, a significant difference (p=0.01) was identified between Eastern Cape and Gauteng healthcare sector concerning the nurse category that was involved in the adverse events.

Midwives were more likely to be involved in adverse events in the Gauteng healthcare sector.

Table 5.47: Nurse category involved (N=177)

	ECP	GP	Total
Category involved			
Professional Nurse	n=17 (19.5%)	n=5 (5.6%	n=22(12.4 %)
Enrolled Nurse	n=3 (3.4%)	n=1 (1.1%)	n=4 (2.3 %)
Enrolled nursing assistant	n=2 (2.3%)	n=0 (0.0%)	n=2 (1.1 %)
Midwife	n=65 (74.7%)	n=84 (93.3%)	n=149 (84.2 %)
Total	**n=87 (100%)**	**n=90 (100%)**	**N=177 (100.0%)**

5.3.6 Section F: Principal incident Type, severity of adverse event and factors contributing to the adverse event (Questions 38-39)

This section refers to the principal incident type, the severity of adverse events and factors contributing to the adverse events.

In each adverse event, more than one incident type and multiple factors contributed to the adverse event.

5.3.6.1 Question 38: Adverse event by principal incident type (N=203)

The analysis shows that the most common principal type was clinical management, n=178 (87.7%), followed by organisational n=25 (12. 3%) and human behavior n=25 (12.3%) as shown in table 5.48.

There was no statistically significant difference identified between the Eastern Cape and Gauteng healthcare sectors regarding the principal type as shown when a Pearson Chi-square test was applied.

The p values were:

- Clinical management (p=0.323)
- Human behavior problems: (p=0.940)
- Organisational: (p=0.570)

Table 5.48: Adverse event by principal type

	ECP	GP	Total
Adverse event by principal type			
Clinical management	n=95 (90.5%)	n=83 (84.7%)	n=178 (87.7 %)
Human behavior problems	n=13 (12.4%)	n=12 (12.2%)	n=25 (12.3 %)
Organisational	n=15 (14.3%)	n=13 (13.3%)	n=28 (13.8 %)
Administrative	n=3 (2.9%)	n=2 (2.0%)	n=5 (4.9 %)

5.3.6.2 Question 39: The severity of the adverse events according to the safety assessment code (SAC) matrix (N=203) (SA Health Risk Management Framework, nd).

Table 5.49 shows that the majority of the adverse events were extreme n=180 (88.7%) and n=22 (10.8%) adverse events were major.

The Pearson Chi-square statistical test revealed a significant difference (p=0.01) identified between the Eastern Cape and Gauteng healthcare sector concerning the severity of adverse events. Gauteng healthcare sector was more likely to have extreme adverse events.

Table 5.49: Severity of adverse event using the SAC (N=203)

	ECP	GP	Total
The severity of adverse events using the SAC			
Extreme	n=84 (80%)	n=96 (98.0%)	n=180 (88.7 %)
Major	n=20 (19.0%)	n=2 (2.0%)	n=22 (10.8) %
Moderate	n=1 (1.0%)	n=0 (0.0%)	n=1 (0.5 %)
Minor	n=0(0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Insignificant	n=0 (0.0%)	n=0 (0.0%)	n=0 (0.0 %)
Total	**n=105 (100%)**	**n=98 (100%)**	**N=203 (100.0 %)**

5.3.6.3 Question 40: Factors contributing to the adverse event (N=203)

Various factors contributed to the occurrence of adverse events that resulted in malpractice litigation in nursing practice among n=203 patients in the study population. These included failing to apply guidelines/protocols in 186 (91.6%) of cases, followed by clinical manifestation not responded in n=56 (76.8 %) of cases, poor monitoring in n=156 (76.8%) of cases, accumulation of omissions in n=105 (51.7%) cases, accumulation of errors in=72 (35.5 %) cases, failing to give treatment as required in n=81 (39.9%) cases and system failure in=25 (12.3%) cases. This is shown in table 5.50.

The Pearson Chi-square statistical test revealed significant differences between the Eastern Cape and Gauteng healthcare sector concerning the factors that contributed to adverse events. Specifically, clinical manifestations not responded to (p=0.01), poor monitoring (p=0.01), accumulation of omissions (p=0.01) and accumulation of errors (p=0.01).

Clinical manifestations not responded to and poor monitoring were more inclined to contribute to adverse events in the Gauteng healthcare sector. While in the ECP healthcare sector accumulation of omissions and accumulation of errors were more likely to contribute to adverse events.

Table 5.50: Contributing factors to adverse events

	ECP	GP	Total
Contributing factors to adverse events			
Clinical manifestation not responded to	n=74(70.5%)	n=87 (88.8%)	n=161 (79.3 %)
Poor monitoring	n=72(68.6%)	n=84 (85.7%)	n=156 (76.8 %)
Failing to apply guidelines / protocols	n=94 (89.5%)	n=92 (93.9%)	n=186 (91.6 %)
Failing to give treatment as required	n=68 (64.8%)	n=13 (13.3 %)	n=81 (39.9 %)
Incorrect Treatment	n=11 (10.5%)	n=9 (9.2%)	n=20 (9.9 %)
Accumulation of omissions	n=77 (73.3%)	n=28 28.6%)	n=105 (51.7%)
Accumulation of errors	n=61 (58.1%)	n=11 (11.2%)	n=72 (35.5 %)
System failures	n=13 (12.4%)	n=12 (12.2%)	n=25 (12.3 %)
Behavioral e.g. attitude	n=0 (0.0%)	n=6 (6.1%)	n=6 (3.0 %)
Lack of supervision	n=2 ((1.9%)	n=0 (0.0%)	n=2 (1.0)
Lack of training	n=0 (0.0%	n=0 (0.0%)	n=0 (0.0)
Lack of Knowledge	n=0 (0.0%)	n=2 (2.0%)	n=2 (1.0)

5.4 SUMMARY

The results have indicated that the majority of the adverse events which led to malpractice litigation in nursing practice occurred in the labour wards in both the Eastern Cape and Gauteng public healthcare sectors.

A statistically significant (p=0.01) difference was identified between the Eastern Cape and Gauteng public healthcare sectors concerning the environment where adverse events that led to malpractice litigation occurred.by applying a Pearson Chi-square test. Adverse events leading to malpractice litigation in nursing practice were more likely to occur in the labour wards of the Gauteng public healthcare sector.

Factors contributing to adverse events that led to malpractice litigation in nursing practice are predominantly failing to apply guidelines / protocols (91.6%), clinical manifestation not responded to (79.3%) and poor monitoring (76.8%) were identified as factors that contribute to the occurrence of the adverse events that may lead to malpractice litigation in public healthcare sectors of Gauteng and Eastern Cape provinces

Furthermore, the majority of adverse events which led to malpractice litigation suffered by the study population were classified as extreme (88.7%) in severity, according to the SAC and had their quality of life permanently affected.

5.5 CONCLUSION

In this chapter, the researcher described the statistical analysis of the data obtained in the public sector, specifically the Gauteng and Eastern Cape healthcare sectors through an audit of 203 trial bundles.

Objective 1 that was set for this study: To conduct a retrospective audit of adverse events resulting in malpractice litigation described in trial bundles from cases in the public healthcare sectors in the Gauteng and Eastern Cape provinces was adequately addressed.

The hypotheses set for phase1 of this study:

H_1 "There are differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in the public hospitals in Gauteng and the Eastern Cape provinces" **was accepted.**

H_0 "There are no differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in the public hospitals in Gauteng and the Eastern Cape provinces" **was rejected.**

CHAPTER 6: DATA ANALYSIS: COMPARISON BETWEEN PUBLIC AND PRIVATE HEALTHCARE SECTORS

6.1 INTRODUCTION

An audit of trial bundles aimed at conducting a retrospective study of adverse events which led to malpractice litigation in the Eastern Cape Province (ECP) and Gauteng public healthcare sectors was conducted by the PhD student and completed in phase 1 of this study.

Two master's degree students individually completed an audit of adverse events which led to malpractice litigation in the Western Cape Province (WCP) and Gauteng Province (GP) private healthcare sectors.

In this chapter, the researcher presents a comparative statistical analysis between the data of the Western Cape Province (WCP) and Gauteng private healthcare sectors (n=122) and the Eastern Cape Province (ECP) and Gauteng public healthcare sectors' (n=203).

This chapter covers the degree to which objective 2 of this study met, "To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces", and to consider the hypothesis set for this study:

H_0: There are no statistical differences between the public and private analyses of adverse events which led to malpractice litigation in nursing practice.

H_1: There are statistical differences between the public and private analyses of adverse events which led to malpractice litigation in nursing practice.

The data revealed the following difference between 203 public and 122 private patients experiencing adverse events:

- The study found a significant difference between the groups, with 86% of the public group being female and 56% in the private group. A statistically significant difference (p=0.01) was identified by applying a Pearson Chi-square statistical test between the public and private healthcare sectors concerning gender.
- Patients in the public sector who experienced an adverse event were more likely to have been in labour and admitted to midwifery/obstetric units. In the public healthcare sector 51.6% patients were admitted to the midwifery/obstetric units and 15.6% to the private healthcare sector. A statistically significant difference (p=0.01) was identified between the public and private healthcare sectors concerning the discipline patients were admitted to before the adverse event occurred.

6.2 DESCRIPTIVE DATA ANALYSIS

The data used had been extracted from trial bundles containing nursing documents, complaints from the defendant and the plaintiff sent to the lawyers, notes written by expert witnesses about the aetiology of adverse events recorded in the trial bundles.

The data were merged with the assistance of the biostatistician, who is a co-investigator in the main study.

The data collection instruments and spreadsheet of the data collected in the Eastern Cape Province (ECP), Gauteng public healthcare sectors and Western Cape, Gauteng private healthcare sectors were aligned and used to merge the data.

Data will be presented in frequencies, tables and other graphic means. In total, the researcher will present an analysis of data collected from n=325 malpractice litigation trial bundles.

Checking, rechecking and crosschecking of the merged data were carried out with the assistance of the supervisor who is the principal investigator of the main study. The purpose of crosschecking the data was to ensure the validity of the data that may affect the study. Each column of the tables showing the merged data were cross-checked with 99 representing not applicable. The data not “available” was collapsed into one column with “not documented” and this was coded “98”. The codes 98 and 99 were used as guided by the biostatistician.

The tests that were applied to analyse data included:

- The IBM Statistical Package for the Social Sciences (SPSS) version 25: to create charts, tables and numerical statistical measures to assist in the interpretation of the results.
- Pearson Chi-Square test was used to determine whether there were statistical differences between the variables using a 95% confidence interval. For this study, the Pearson Chi-square test at a p-value of ($p \leq 0.05$) was used to determine statistically significant differences between variables.
- The Pearson Chi-square test was applied on a 95% confidence interval to determine any statistically significant differences between the public and private healthcare concerning the factors that may have led to adverse events.

6.3 SECTION A: LITIGATION (QUESTION 1-2)

In this section, the researcher presents the data reflecting the province where the adverse event occurred and whether the case was settled out of court or presented in court.

6.3.1 Question 1: Province where the malpractice litigation occurred (N=325)

Table 6.1 shows that in the private sector, n=81 (33.6%) of the malpractice litigation cases occurred in the Western Cape Province and n=41(33.6%) in Gauteng. While in the public sector n=98 (48.3%) of malpractice litigation cases occurred in Gauteng Province and n=105 (51.7%) in Eastern Cape Province.

In summary n=203 (62.4%) cases occurred in the public sector and n=122 (37.5%) in the private sector. In total, the trial bundles that were audited for this study are N=325(100%), an audited rate of 81.3% of the N=400 malpractice litigation cases as initially planned in consultation with the statistician.

Table 6.1: Province where the malpractice litigation occurred (N=325)

Province	Public	Private	Total
GP	n=98 (48.3%)	n=41 (33.6%)	n=139 (42.8%)
EC	n=105 (51.7%)	n=0 (0.0%)	n=105 (32.3%)
WC	n=0 (0.0%)	n=81 (66.4%)	n=81 (24.9%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.3.2 Question 2: Case presentation (N=325)

As shown in table 6.2 n=90(27.7%) of the trial bundles audited were presented and settled out of court in the private sector, and all (n=203) audited cases in the public sectors were presented in the High Court.

Applying the Pearson Chi-square statistical test, a significant difference was identified between how the cases were presented and settled in the private and public health care sector (p=0.01).

The private sector was more likely to settle a malpractice case out of court. In this study, all (100%) of the malpractice cases that occurred in the public sector were presented in the High Court.

Table 6.2: Case presentation

How were cases presented	Public	Private	Total
In High court	n=203 (100%)	n=32 (9.8%)	n=235 (72.3%)
Settled out of court	n= 0(0%)	n=90 (27.7%)	n=90 (27.7%)
Total	**n=203 (100%)**	**n=122 (100%)**	**N=325 (100%)**

6.4 SECTION B: DEMOGRAPHIC DATA (QUESTIONS 3-11)

In this section, the patient's age, gender, marital status, dependents (if applicable), employment, social habits and pre-existing medical history are described.

6.4.1 Question 3: Age of the patient (N=325)

The age of the patients who experienced an adverse event that resulted in malpractice litigation ranged from 1 year to 70-years in the public sector with a mean age of 28.86 and standard deviation of 10.7 applying the t-test. The mean age in the private sector was 34.56 with an age range of 0-years to 96-years and a standard deviation of 24.4.

Applying the Pearson Chi-square test, a statistically significant difference (p=0.01) was identified between the private and public healthcare sectors concerning the age range of patients who had experienced an adverse event.

Younger patients were more likely to have an adverse event in the public healthcare sector.

6.4.2 Question 4: Gender (N=325)

The majority of the patients were female, n=240 (73.8%) and n=85 (26.2%) were male, as shown in table 6.3. A statistically significant difference (p=0.01) was identified between public and private healthcare with regards to gender by applying a Pearson Chi-square statistical test. The public healthcare sector was more likely to have more female patients admitted.

Table 6.3: Gender (N=325)

Gender	Public	Private	Total
Female	n=175 (86.2%)	n=65 (53.3%)	n=240 (73.8%)
Male	n=28 (13.8%)	n=57 (46.7%	n=85 (26.2%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.3 Question 5: Marital status (N=325)

Table 6.4 shows that the majority of the patients were single, n=191 (58. 8%) followed by those that were married n=104 (32.0%). The Pearson Chi-square statistical test identified a significant difference (p=0.01) between the public and private healthcare sectors concerning marital status.

In the public healthcare sector, the patients who had an adverse event were more likely to be single.

Table 6.4: Marital status (N=325)

Marital status	Public	Private	Total
Single	n=140 (69.0 %)	n=51 (41.8 %)	n=191 (58.8 %)
Married	n=53 (26.1%)	n=51 (41.8 %)	n=104 (32.0) %
Partner	n=2 (1.0 %)	n=6 (4.9 %)	n=8 (2.5 %)
Widowed/Widower	n=4 (2.0 %)	n=13 (10.7 %)	n=17 (5.2%)
Divorced	n=4 (2.0 %)	n=1(0.8 %)	n=5 (1.5%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.4 Question 6: Dependents (N=325)

Table 6.5 shows that the majority of patients who had an adverse event had no dependents, n=156 (48.0%), n=55 (16.9%) had one dependent. However, n=46 (14.6%) was not documented. Applying the Pearson Chi-square test, a statistically significant difference was identified between the private and public healthcare sectors concerning dependents (p=0.01).

The patients who experienced adverse events in the public sector were more likely to have no dependents.

Table 6.5: Dependents (N=325).

Dependents	Public	Private	Total
None	n=121 (59.6 %)	n=35 (28.7 %)	n= 156(48.0 %)
One	n=39 (19.2 %)	n=16 (13.1)	n=55 (16.9 %)
Two	n=7(3.4 %)	n=25 (20.5)	n=32 (9.8 %)
Three	n=4 (2.0 %)	n=8 (6.6)	n=12 (3.7 %)
>Three	n=1 (0.5 %)	n=7 (5.7)	n=8 (2.5 %)
Not documented	n=29 (14.3 %)	n=17 (13.9)	n=46 (14.2 %)
99 (Child/neonate)	n=2 (1.0 %)	n=14 (11.5)	n=16(4.9 %)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.5 Question 7: Disability on admission (N=325)

Table 6.6 shows that n=305 (93.8%) patients had no disability on admission, and n=20 (6.2%) had a disability. There is no statistically significant difference in applying the Pearson Chi-square test (p=0.464) between the public and private healthcare sectors concerning disability.

Table 6.6: Disability (N=325)

Disabilities	Public	Private	Total
Yes	n=10(4.9 %)	n=10 (8.2 %)	n=20 (6.2%)
No	n=193 (95.1 %)	n=112 (91.8 %)	n=305 (93.8%)
Total	**n=203 (100.0 %)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.6 Question 8: Social habits (Smoking, Unsolicited drugs, Alcohol) (N=325)

Social habits are presented in the tables which will follow.

6.4.6.1 Smoking

In most trial bundles n=172 (52.9%) as shown in table 6.7 about whether patients smoked or not were not documented.

Applying a Pearson Chi-square test, a statistically significant difference (p=0.01) was identified between the private and public healthcare sectors concerning smoking.

In the public healthcare sector, nursing staff were more likely not to document on admission whether the patients smoked or not.

Table 6.7: Smoking (N=325)

Smoking	Public	Private	Total
Yes	n=10 (4.9 %)	n=16 (13.1%)	n=26 (8.0 %)
No	n=41 (20.2%)	n=46 (37.7%)	n=87 (26.8%)
Not documented	n=147 (72.4%)	n=25 (20.5%)	n=172 (52.9%)
99 (not applicable)	n=5 (2.5%)	n=35 (28.7%)	n=40 (12.3%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.6.2 Unsolicited drugs

As shown in table 6.8, n=67(20.6%) were not using unsolicited drugs, and it was not documented whether n=214 (65.8%) used unsolicited drugs or not. Applying the Pearson Chi-square test, a statistically significant difference (p=0.01) was identified between the public and private healthcare sectors concerning unsolicited drugs.

In the public healthcare sector, nursing staff were more likely not to document whether patients were using drugs or not.

Table 6.8: Unsolicited drugs (N=325)

Unsolicited drugs	Public	Private	Total
Yes	n=4 (2.0) %	n=0 (0.0%)	n=4 (1.2%)
No	n=33 (17.6%)	n=34 (27.9%)	n=67 (20.6%)
Not documented	n=161 (79.3%)	n=53(43.4%)	n=214 (65.8%)
99 (not applicable)	n=5(2.5%)	n=35 (28.7%)	n=40 (12.3%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.6.3 Alcohol

Table 6.9 shows that the use of alcohol was not documented in the majority, n=176 (54.2%) of cases. Applying the Pearson Chi-square test, a statistically significant difference (p=0.01) was identified between the public and private healthcare sectors concerning alcohol.

In the public healthcare sector, the nursing staff were more likely not to document on admission whether patients were using alcohol or not.

Table 6.9: Alcohol (N=325)

Alcohol	Public	Private	Total
Yes	n=10 (4.9 %)	n=18 (14.8 %)	n=28 (8.6%)
No	n=40 (19.7 %)	n=41 (33.6%)	n=81 (24.9%)
Not documented	n=148 (72.9%)	n=28 (23.0%)	n=176 (54.2%)
99 (not applicable)	n=5 (2.5 %)	n=35 (28.7%)	n=40 (12.3%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.7 Question 9: Underlying medical conditions on admission, e.g. hypertension (N=325)

Table 6.10 shows that the majority, n=205 (63.1%) of the patients, had no underlying medical condition on admission while n=111 (34.2%) patients in the study suffered from medical conditions.

Applying the Pearson Chi-square statistical test, a statistically significant difference (p=0.04) was identified between the private and public healthcare sectors concerning underlying medical conditions before admission.

Patients admitted to the public healthcare sector were more likely to have no underlying medical conditions on admission.

Table 6.10: Underlying medical conditions on admission, e.g. hypertension (N=325)

Medical condition	Public	Private	Total
Yes	n=55 (27.1%)	n=56 (45.9%)	n=111 (34.2%) (p=0.04)
No	n=141 (69.5%)	n=64 (52.5%)	n=205
Not Documented	n=7 (3.4%)	n=2 (1.6%)	n=9 (2.8%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.8 Question 10: Employment at the time of admission to hospital (N=325)

Majority of the patients in this study were not employed on admission n=185 (56.9%) while 67 (20.6%) patients were employed, and n=15 (4.6%) were self-employed as shown in table 6.11. A statistically significant difference (p=0.01) was identified between the private and public healthcare sectors regarding employment.

In the public healthcare sector, the patients were more likely to be unemployed.

Table 6.11: Employment (N=325)

Employment	Public	Private	Total
Employed	n=21(10.3%)	n=46 (37.7%)	n=67(20.6%)
Self Employed	n=8(3.9%)	n=7(5.7%)	n=15 (4.6%)
Not Employed	n=168(82.8%)	n=17 (13.9%)	n=185 (56.9%)
Pensioner	n=1 (0.5%)	n=17 (13.9%)	n=18(5.5%)
NA (child)	n=5 (2.5%)	n=35 (28.7%)	n=40 (12.3%)
Total	**n=203 (100.0%)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.4.9 Question 11: Type of Employment (N=325)

Table 6.12 shows the type of employment the patient was involved in before the adverse event. The option labelled 99 indicated unemployed n=216 (66.5%).

The remaining patients were in administrative positions n=23 (7.1%), followed by business n=18(5.5%). Applying the Pearson Chi-Square test, a statistically significant difference (p=0.01) was identified between the public and private healthcare sector regarding the type of employment. The patients admitted to the public healthcare sector were more likely to be unskilled.

Table 6.12: Type of Employment (N=325)

Type of Employment	Public	Private	Total
Professional	n=0 (0.0 %)	n=13 (10.7%)	n=13 (4.0%)
Technical	n=1 (0.5%)	n=4 (3.3%)	n=5(1.5%)
Business	n=5 (2.5%)	n=13 (10.7%)	n=18(5.5%)
Administrative	n=6 (3.0 %)	n=17 (13.9%)	n=23 (7.1%)
Tradesman	n=0 (0.0%)	n=2 (1.6%)	n=2(0.6%)
Labourer/unskilled	n=17 (8.5%)	n=1 (0.8 %)	n=18 (5.5%)
Other	n=0 (0.0%)	n=30 (24.6%)	n=30 (9.2%)
99 (not applicable)	n=174 (85.7%)	n=42 (34.4%)	n=216(66.5 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5 SECTION C: HOSPITALISATION (QUESTIONS 12-31)

This section refers to the phases of the nursing process and management of the patient.

6.5.1 Question 12: Availability of nursing ward notes for auditing N=325

All ward notes n=325 (100 %) were available for auditing.

Table 6.13: Availability of the nursing ward notes (N=325)

Availability of the nursing ward notes	Public	Private	Total
Yes	n=203 (100%)	n=122 (100%)	n=325 (100%)
No	n=0 (0.0 %)	n=0 (0.0 %)	n=0 (0.0%)
Total	**n=203 (100.0 %)**	**n=122 (100.0%)**	**N=325 (100.0%)**

6.5.2 Question 13: Completeness of the nursing process documents (N=325)

Table 6.14 shows that the majority of the trial bundles audited, n=190(58.5%) of the nursing process documents were complete, while 135 (41.5%) were incomplete.

A statistically significant difference (p=0.01) was identified applying the Pearson Chi-square statistical test between private and public healthcare sectors with specific reference to the completeness of the nursing ward notes.

The private sector was more likely to have complete nursing ward notes.

Table 6.14: Completeness of the nursing ward notes (N=325)

Completeness of the nursing ward notes	Public	Private	Total
Complete	n=75 (36.9 %)	n=115(94.3%	n=190 (58.5%)
Incomplete	n=128 (63.1%)	n=7 (5.7%)	n=135 (41.5%)
Total	**n=203 (100.0)**	**n=122 (100.0)**	**N=325 (100.0%)**

6.5.3 Question 14: Reason for admission (N=325)

Table 6.15 shows that the majority of patients n=166 (51.1%) in this study were admitted for emergency conditions, and for sickness n=63 (19.4%).

A statistically significant difference was identified applying the Pearson Chi-Square statistical test (p=0.01) between the private and public healthcare sectors concerning reasons for admission.

The reasons for admission in the public healthcare sector were more likely to be due to an emergency.

Table 6.15: Reason for admission (N=325)

Reasons for admission	Public	Private	Total
Elective surgery	n=8 (3.9%)	n=30 (24.6 %)	n=38 (11.7 %)
Planned	n=3 (1.5 %)	n=14 (11.5 %)	n=17 (5.2 %)
Emergency	n=136 (67.0 %)	n=30(24.6 %)	n=166 (51.1 %)
Sick	n=18 (8.9 %)	n=45(36.9 %)	n=63 (19.4 %)
Other	n=38 (18.7 %)	n=3 (2.5 %)	n=41 (12.6 %)
Total	**n=203(100.0) %**	**n=122(100.0 %)**	**N=325 (100.0%)**

6.5.4 Question 15: Discipline to which the patient was admitted before the adverse event (N=325)

The majority of the patients were admitted to the midwifery/obstetric units, n=168 (51.6%), followed by medical n=45 (13.8 %), trauma n=34 (10.5 %) and general surgery n=16 (4.9%). This is shown in table 6.16.

A statistically significant difference was identified applying the Pearson Chi-Square statistical test (p=0.01) between the private and public healthcare sectors concerning reasons for admission. Patients in the public healthcare sector were more likely to have been admitted to midwifery/ obstetric units.

Table 6.16: Discipline (N=325)

Discipline	Public	Private	Total
Cardiology	n=0 (0.0 %)	n=4 (3.3 %)	n=4 (1.2 %)
Gynaecology	n=1 (0.5 %)	n=9 (7.4 %)	n=10(3.1 %)
Medical	n=21 (20.0 %)	n=25 (20.5 %)	n=45(13.8 %)
Midwifery	n=149(73.4%)	n=19 (15.6 %)	n=168(51.6%)
Neonatology	n=1 (0.5 %)	n=9 (7.4 %)	n=10 (3.1 %)
Nephrology	n=0 (0.00 %)	n=2 (1.6 %)	n=2 (o.6 %)
Neurosurgery	n=2 (1.0 %)	n=5 (%)	n=7 (2.2%)
Neurology	n=0 (0.0%)	n=1 (0.8 %)	n=1(0.3 %)
Orthopaedics'	n=6 (3.0 %)	n=3 (2.5 %)	n=9 (2.8 %)
Ophthalmology	n=1 (0.5 %)	n=1 (0.8 %)	n=2 (0.6 %)
Paediatrics	n=2 (1.0%)	n=4 (12.3)	n=8 (2.5%)
Psychiatry	n=0 (0.0 %)	n=1 (0.8 %)	n=1 (0.3 %)
Trauma	n=18 (8.9 %)	n=16 (13.1 %)	n=34 (10.5 %)
General Surgery	n=1 (0.5 %)	n=15(12.3)	n=16 (4.9%)
Cardiac Surgery	n=0 (0. 0 %)	n=4 (3.3)	n=4 (1.2 %)
Other	n=0 (0.0%)	n=4 (3.3)	n=4 (1.2 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.5 Question 16: Type of ward/unit the patient was admitted to before the adverse event (N=203)

Most patients were admitted to the labour ward n=159 (51.1%), followed by general wards n=66 (20.3%). Applying the Pearson Chi-square statistical test, a significant difference (p=0.01) was identified between the private and public healthcare sector with reference to the units where the patients were admitted before the adverse event occurred. The public healthcare sector was more likely to have patients admitted to the labour ward. Furthermore, the private sector was more likely to have patients admitted to general wards.

Table 6.17: Type of wards/units

Type of wards/units	Public	Private	Total
Emergency/ Casualty	n=30 (14.8%)	n=24 (19.7%)	n=54(16.6%)
General ward	n=19 (9.4%)	n=47(38.5%)	n=66 (20.3%)
Paediatrics	n=6 (3.0%)	n=6 (4.1%)	n=12 (3.7%)
ICU	n=1 (0.5%)	n=17 (13.9%)	n=18 (5.5%)
Antenatal	n=4 (2.0%)	n=0 (0.0%)	n=4 (1.2%)
Labour	n=143(70.4%)	n=16 (13.1%)	n=159 (51.1%)
Postnatal ward	n=0 (0.0%)	n=12 (9.8%)	n=12 (3.7%)
Total	**n=203 (100%)**	**n=122 (100%)**	**N=325**

6.5.6 Nursing process:

6.5.6.1 Question 17: Status of the initial assessment (N=325)

Table 6.18 indicate that n=175 (53.8%) of the initial assessments were incomplete, n=119 (36.6%) were complete and n=31(9.5%) were not done.

A statistically significant difference was identified applying the Pearson Chi-Square statistical test (p=0.01) between the private and public healthcare sectors concerning the initial assessment. The initial assessment of patients in the public healthcare sector was more likely to be incomplete.

Table 6.18: Status of the Initial assessments (N=325)

Status of the Initial assessments	Public	Private	Total
Complete	n=52 (25.6 %)	n=67(54.9 %)	n=119(36.6 %)
Incomplete	n=148(72.9 %)	n=27 (22.1 %)	n=175 (53.8 %)
Not Done	n=3 (1.5 %)	n=28(23.0 %)	n=31 (9.5 %)
Total	**n=203 (100.0)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.2 Question 18: The status of the care plan (N=325)

Table 6.19 shows n=155 (47.7%) care plans were incomplete, n=121(37.2%) were complete and n=49 (15.1%) were not done. Applying the Pearson Chi-Square test, a statistically significant difference (p=0.01) was identified between private and public healthcare concerning the status of care plans.

The status of care plans in the public healthcare sector was more likely to be incomplete than those of a private healthcare sector.

However, care plans in the private healthcare sector were more likely not to be done than in the public sector.

Table 6.19: Status of the care plan (N=325)

Status of the care plan	Public	Private	Total
Complete	n=44 (21.7 %)	n=77 (63.1 %)	n=121 (37.2 %)
Incomplete	n=144 (70.9 %)	n=11 (9.0 %)	n=155 (47.7 %)
Not done	n=15 (7.4 %)	n=34 (27.9 %)	n=49 (15.1 %)
Total	**n=203 (100.0)**	**n=122 (100.0)**	**N=325 (100.0)**

6.5.6.3 Question 19: Implementation of care plans (N=325)

As illustrated in table 6.20, n= 239 (73.5%) of the care plans were implemented, while n= 86 (26.5%) were not implemented. Pearson Chi-square test indicated a statistically significant

difference (p=0.01) between private and public healthcare sectors concerning the implementation of care plans.

Care plans of patients in the public healthcare sector were more likely to be implemented.

Table 6.20: Implementation of care plans (N=325)

Implementation of care plans	Public	Private	Total
Yes	n=161 (79.3 %)	n=78(63.9 %)	n=239 (73.5 %)
No	n=42 (20.6 %)	n=44 (36.1 %)	n=86 (26.5 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0)**

6.5.6.4 Question 20: Special care plans were required (N=325)

The majority of patients n=247 (76.0%) of the trial bundles audited required special care plans and n=78 (24.0%) did not, as shown in table 6.21. The Pearson-Chi Square test revealed a statistical difference (p=0.01) between the public and private healthcare sectors concerning patients who required special care plans.

Patients were more likely to require special care plans in the public healthcare sector.

Table 6.21: Special care plans required (N=325)

Special Care plans required	Public	Private	Total
Yes	n=187 (92.1 %)	n=60 (49.2 %)	n=247 (76.0 %)
No	n=16 (7.9)	n=62 (50.8 %)	n=78 (24.0 %)
Total	**n=203 (100.0)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.5 Question 21: Status of the special care plan (N=325)

Table 6.22 shows that n=151(46.5%) of the special care plans were incomplete, n=70 (21.5%) were complete, and n=26 (8.0%) of the patients had no special care plans formulated.

A statistically significant difference (p=0.01) was shown applying the Pearson Chi-Square test between private and public healthcare sectors concerning the status of special care plans.

The public healthcare sector was more likely to have incomplete special care plans.

Table 6.22: Status of the special care plan (N=325)

Special Care plans required	Public	Private	Total
Complete	n=35 (17.2 %)	n=35 (28.7 %)	n=70 (21.5 %)
Incomplete	n=139 (68.5 %)	n=12 (9.8 %)	n=151 (46.5 %)
No done	n=13 (6.4 %)	n=13 (10.7 %)	n=26 (8.0 %)
99 (not applicable)	n=16 (7.8 %)	n=62 (50.8 %)	n=78 (24.0 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0)**	**N=325 (100.0 %)**

6.5.6.6 Question 22: Implementation of special care plans (N=325)

Table 6.23 shows that n=176 (54.2%) special care plans were implemented and n=71 (21.8%) were not implemented although there was a need to implement.

A statistically significant difference (p=0.01) was identified when applying the Pearson Chi-square test between public and private healthcare sectors concerning the implementation of special care plans. Nursing staff in the public healthcare sector were more likely to implement special care plans.

Table 6.23: Special care plans implemented (N=325)

Special care plans implemented	Public	Private	Total
Yes	n=141 (69.5%)	n=35(28.7 %)	n=176(54.2 %)
No	n=46(22.7 %)	n=25(20.5 %)	n=71(21.8 %)
99 (not applicable)	n=16 (7.9 %)	n=62 (50.8 %)	n=78 (24.0 %)
Total	**n=203(100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7 Question 23: Vital signs Monitored (N=325)

The results on monitoring of vital signs are presented in this question.

6.5.6.7.1 Blood pressure monitoring (N=325)

Table 6.24 illustrates the results of blood pressure monitoring. The results show that blood pressure monitoring was incompletely done in n=172 (52.9%) cases, or not done at all in n=29(8.9%) cases. Only n=124 (38.2%) patients had their blood pressure monitored.

Applying the Pearson Chi-Square test a statistically significant difference (p=0.01) was identified between public and private healthcare sectors concerning blood pressure monitoring.

In the private healthcare sector, blood pressure monitoring of patients was more likely to be done.

Table 6.24: Blood pressure monitored (N=325)

Blood pressure	Public	Private	Total
Complete	n=42 (20.7 %)	n=82 (67.2 %)	n=124 (38.2 %)*
Incomplete	n=161 (79.3 %)	n=11 (9.0 %)	n=172 (52.9 %)
Not Done	n=0 (0.0 %)	n=29 (23.8 %)	n=29 (8.9 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.2 Pulse monitoring (N=325)

Table 6.25 shows that n=140 (43.1%) patients' pulse were monitored completely while most patients n=184(56.6%) were not monitored completely.

A statistical significant difference was identified when applying a Pearson Chi-Square test (p=0.01) between the public and private healthcare sectors concerning pulse monitoring.

Pulse monitoring of patients in the private healthcare sector was more likely to be done completely.

Table 6.25: Pulse monitored (N=325)

Pulse	Public	Private	Total
Complete	n=42 (20.7 %)	n=98 (80.3 %)	n=140 (43.1%)
Incomplete	n=160 (78.8 %)	n=24 (19.7 %)	n=184(56.6 %)
Not Done	n=1 (0.4 %)	n=0 (0.0%)	n=1 (0.3%)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.3 Foot pulse monitoring (N=325)

Table 6.26 shows that out of n=57 patients that needed foot pulse monitoring, n= 20 (6.2%) were completely done, n=15 (4.6%) were incompletely done and 22 (6.8%) were not done.

A statistically significant difference was identified between private and public healthcare sectors with regard to foot pulse monitoring by applying the Pearson Chi-Square test (p=0.01).

Table 6.26: Foot pulse monitored (N=325)

Foot pulse	Public	Private	Total
Complete	n=5 (2.5 %)	n=15 (12.3 %)	n=20 (6.2 %)
Incomplete	n=4 (2.0 %)	n=11 (9.0 %)	n=15 (4.6 %)
Not Done	n=6 (3.0 %)	n=16 (13.1 %)	n=22 (6.8 %)
99 (not applicable)	n=188 (92.6 %)	n=80 (65.6 %)	n=268 (82.5 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.4 Foetal heart monitoring (N=325)

The research results showed that of the n=172 patients requiring foetal heart monitoring, only n=18(5.5%) were monitored completely, n=145 (44.6%) were not monitored completely, and n=9 (2.8%) were not monitored at all. This is shown in table 6.27.

A statistically significant difference (p=0.01) was shown between private and public healthcare sectors concerning foetal heart monitoring applying the Pearson Chi-square test.

The public healthcare sector was more likely to have incomplete foetal heart monitoring.

Table 6.27: Foetal heart monitored (N=325)

Foetal heart monitored	Public	Private	Total
Complete	n=10 (4.9 %)	n=8 (6.6 %)	n=18 (5.5 %)
Incomplete	n=143 (70.4%)	n=2 (1.6%)	n=145 (44.6 %)
Not Done	n=1 (0.5%)	n=8 (6.6 %)	n=9 (2.8 %)
99 (not applicable)	n=49(24.1 %)	n=104 (85.2 %)	n=153 (47.1 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325(100.0 %)**

6.5.6.7.5 Respiration monitoring (N=325)

Table 6.28 shows that of the n=325 study patients requiring respiration monitoring, n=178 (54.8%) were incompletely monitored, n=134 (41.2%) were monitored completely, and n=13 (4.0%) were not monitored at all.

A statistically significant difference was identified between the public and private healthcare sectors concerning the monitoring of respiration by applying the Pearson-Chi-square test (p=0.01).

In the public healthcare sector, respirations were more likely to be incompletely monitored.

Table 6.28: Respiration monitoring (N=325)

Respirations monitored	Public	Private	Total
Complete	n=43 (21.2 %)	n=91 (74.6 %)	n=134 (41.2 %)
Incomplete	n=156 (76.8 %)	n=22 (18.0 %)	n=178 (54.8 %)
Not Done	n=4 (2.0 %)	n=9 (7.4 %)	n=13 (4.0 %)
Total	**n=203 (100 %)**	**n=122 (100 %)**	**N=325 (100 %)**

6.5.6.7.6 Temperature monitoring (N=325)

Table 6.29 shows that of the n=325 study patients requiring temperature monitoring n=178 (54.8%) patients were incompletely monitored, n=131 (40.3%) were monitored completely and n=16 (4.9%) were not monitored at all. A statistically significant difference was identified between

the public and private healthcare sectors concerning temperature monitoring by applying the Pearson Chi-square test (p=0.01).

Temperatures in the public healthcare sector were more likely to be incompletely monitored.

Table 6.29: Temperature monitored (N=325)

Temperature monitored	Public	Private	Total
Complete	n=37 (18.2 %)	n=94(77.0 %)	n=131 (40.3 %)
Incomplete	n=160 (78.8 %)	n=18 (14.8 %)	n=178(54.8 %)
Not Done	n=6 (2.9 %)	n=10 (8.2 %)	n=16 (4.9 %)
Total	**n=203 (100 %)**	**n=122 (100 %)**	**N=325 (100 %)**

6.5.6.7.7 Monitoring intake and output (N=325)

Table 6.30 shows that of n=233 study patients that needed intake and output monitoring, only n=80(24.7%) were monitored completely, n=123(38.0%) were monitored incompletely, and n=30 (9.2%) were not monitored at all.

A statistically significant difference was shown between the public and private healthcare sectors concerning the monitoring of intake and output by applying the Pearson-Chi-square test (p=0.01).

The private healthcare sector was more likely to monitor the intake and output of patients

Table 6.30: Intake and output monitored (N=325)

Intake and output monitored	Public	Private	Total
Complete	n=20 (9.9 %)	n=60 (49.2 %)	n=80 (24.7 %)
Incomplete	n=88 (43.3 %)	n=35 (28.7 %)	n=123 (38.0 %)
Not Done	n=13 (6.4 %)	n=17 (13.9 %)	n= 30 (9.2 %)
99 (not applicable)	n=82 (40.4%)	n=10 (8.2 %)	n=92 (28.3 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.8 Weight monitoring (N=325)

Table 6.31 shows that n=289 study patients required weight monitoring, of which n= 55 (16.9%) were monitored incompletely, and n=42 (12.9 %) were not monitored.

Applying the Pearson Chi-Square test, a significant statistical difference was identified between the public and private healthcare sectors (p=0.01) concerning weight monitoring.

The public healthcare sector was more likely to monitor the weight of patients.

Table 6.31: Weight monitored (N=325)

Weight monitored	Public	Private	Total
Complete	n=142 (70.0 %)	n=48 (39.3 %)	n=190 (58.5 %)
Incomplete	n=25 (12.3 %)	n=30 (24.6 %)	n=55 (16.9 %)
Not Done	n=7 (3.4 %)	n=35 (28.7 %)	n=42 (12.9 %)
99 (not applicable)	n=29 (14.3 %)	n=9 (7.4 %)	n=36 (11.7 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0%)**	**N=325 (100.0 %)**

6.5.6.7.9 Neurological observations (N=325)

Table 6.32 reflects that 80 study patients needed neurological observation monitoring, of which n=28 (8.6%) were monitored completely, n=28 (8.6%) were monitored incompletely, and neurological observations were not monitored n=24 (7.4 %).

A Pearson Chi-Square test was applied, and a significant statistical difference was identified between the public and private healthcare sectors (p=0.01) concerning the neurological observations.

The public health care sector was unlikely to have patients who required monitoring of neurological observations.

Table 6.32: Neurological Observations (N=325)

Neurological Observations monitored	Public	Private	Total
Complete	n=5 (2.5%)	n=23 (18.9 %)	n=28 (8.6 %)
Incomplete	n=5 (2.5%)	n=23 (18.9 %)	n=28 (8.6 %)
Not Done	n=8 (3.9%)	n=16 (13.1%)	n=24(7.4 %)
99 (not applicable)	n=185 (91.1 %)	n=60 (49.2%)	n=245 (75.4%)
Total	**n=203(100.0 %)**	**n=122 (100.0%)**	**N=325(100.0 %)**

6.5.6.7.10 Post spinal surgery observations (N=325)

Sixty patients required post spinal surgery observations, n=19 (5.8%) were monitored completely, n=18 (5.5%) were monitored incompletely and n=23 (7.1%) were not monitored as shown in table 6.33.

A Pearson Chi-Square test was applied, and a significant statistical difference was identified between the public and private healthcare sectors (p=0.01) concerning post spinal surgery observations.

The private healthcare sector was more likely to have incomplete monitoring of post-spinal surgery observations.

Table 6.33: Post spinal surgery observations (N=325)

	Public	Private	Total
Complete	n=9 (4.4 %)	n=10 (8.2 %)	n=19(5.8 %)
Incomplete	n=0 (0.0 %)	n=18(14.8 %)	n=18 (5.5 %)
Not Done	n=7 (3.4 %)	n=16 (13.1 %)	n=23 (7.1 %)
99 (not applicable)	n=187 (92.1 %)	n=78 (63.9 %)	n=265 (81.5 %)
Total	**n=203 (100.0 %)**	**n= 122 (100.0)**	**N=325 (100.0 %)**

6.5.6.7.11 Mental status observations

As shown in table 6.38 n=179 patients required mental status observations, of which n=128 (39.4%) were monitored completely, n=33 (10.2%) were monitored incompletely, and n=18 (5.5%) were not monitored.

A Pearson Chi-square test was applied, and a statistically significant difference was identified (p=0.01) between the public and private healthcare sectors concerning mental status observations.

The public sector was more likely to complete a patient's mental status observations.

Table 6.34: Mental status Observations (N=325)

Metal status observations	Public	Private	Total
Complete	n=97 (47.8 %)	n=31 (25.4 %)	n=128 (39.4 %)
Incomplete	n=6 (3.0 %)	n=27 (22.1 %)	n=33 (10.2 %)
Not Done	n=6 (3.0 %)	n=12 (9.8 %)	n=18 (5.5 %)
99 (not applicable)	n=94 (46.3 %)	n=52 (42.6 %)	n=146 (44.9 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.12 Continuous ECG monitoring

Fifty-eight study patients required continuous ECG monitoring in this study, of which n=34 (10.5%) were monitored completely, n=12 (3.7%) were monitored incompletely, and n= 12 (3.7%) were not monitored**.** A Pearson Chi-square test was applied and a statistically significant difference (p=0.01) was identified between public and private healthcare sectors concerning continuous ECG monitoring. The private healthcare sector was more likely to have complete continuous ECG monitoring.

Table 6.35: Continuous ECG monitoring (N=325)

Continues ECG monitoring	Public	Private	Total
Complete	n=0 (0.0 %)	n=34 (27.9 %)	n=34 (10. 5 %)
Incomplete	n=2 (1.0 %)	n=10 (8.2 %)	n=12 (3.7 %)
Not Done	n=4 (2.0 %)	n=8 (6.6 %)	n=12 (3.7 %)
99 (not applicable)	n=197 (97.0 %)	n=70 (57.4 %)	n=267 (82.2 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.7.13 Continuous oxygen monitoring

Seventy-two patients required continuous oxygen monitoring in this study, of which n= 46 (14.2%) were monitored completely n=15 (4.6%) were monitored incompletely, and n=11 (3.4%) were not monitored**.**

A Pearson Chi-square test was applied and identified a statistical significance (p=0.01) between public and private healthcare sectors concerning continuous oxygen monitoring.

The private healthcare sector was more likely to have complete continuous oxygen monitoring.

Table 6.36: Continuous oxygen monitoring (N=325)

Continues Oxygen monitoring	Public	Private	Total
Complete	n=2 (1.0 %)	n=44 (36.1 %)	n=46 (14.2 %)
Incomplete	n=2 (1. 0 %)	n=13 (10.7) %	n=15(4.6 %)
Not Done	n=4 (2.0 %)	n=7 (5.7 %)	n=11 (3.4 %)
99 (not applicable)	n=195(96.1 %)	n=58 (47.5 %)	n=253 (77.8 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.8 Question 24: Tests done pre-adverse events

Table 6.37 shows required tests not done, haemoglucotest n=162 (60.2%), blood gases n=133 (59.9 %), urea and electrolytes n=114 (44.7 %) and liver function tests n=110 (43.0 %). However, urine tests were done in n=240 (83.0 %) study patients, haemoglobin n=227 (85.5 %), urea and electrolytes n=141 (55.3 %).

A Pearson Chi-square test was applied, and a statistical significant difference between the private, and public healthcare sectors concerning tests specifically haemoglobin (p=0.01) and urinalysis (p=0.01) were identified. These tests were more likely to be done in the public healthcare sector.

These tests were more likely to be done in the public healthcare sector.

Table 6.37: Tests done pre-adverse events

	Done		Total	Not Done		Total
Tests required	Public	Private		Public	Private	
Haemoglucotest (N=269)	n=57 (28.8%)	n=50 (41.0%)	**n=107 (39.8%)**	n=141 (71.2%)	n=21 (17.2%)	**n=162 (60.2%)**
Haemoglobin (N=275)	n=163 (84.5%)	n=64 (52.5%)	**n=227 (82.5%)**	n=30 (15.5%)	n=18 (14.8%)	**n=48 (17.5%)**
Urine tests (N=289)	n=190 (94.1%)	n=50 (41.0%)	**n=240 (83.0%)**	n=12 (5.9%)	n=39 (32.0%)	**n=49 (17.0%)**
Urea and electrolytes (N=255)	n=67 (41.4%)	n=68 (55.7%)	**n=141 (55.3%)**	n=95 (58.6%)	n=19 (15.6%)	**n=114 (44.7%)**
Blood gases (N=222)	n=38 (25.7%)	n=51 (23%)	**n=89 (40.1%)**	n=110 (74.3)	n=23 (10.4%)	**n=133 (59.9%)**
Full blood count (N=256)	n=69 (34.0%)	n=77 (63.1%)	**n=146 (57.0%)**	n=93 (45.8%)	n=17 (13.9%)	**n=110 (43.0%)**
Liver functions (N=193)	n=18 (9.0%)	n=65 (53.3%)	**n=83 (43.0%)**	n=93 (46.3%)	n=17 (13.9%)	**n=110 (57.0%)**
Others (N=20)	n=0 (0.0%)	n=7 (5.7%)	**n=7 (2.2%)**	n=4 (2.0%)	n=9 (7.4%)	**n=13 (4.0%)**
n=1504 (100%)	n=612 (58%)	n=432 (41.1 %)	**n=1044 (69.4 %)**	n=578 (38.4%)	n=163 (10.8%)	**n=741 (31.3%)**

6.5.6.9 Question 25: Test results interpreted (N=325)

Table 6.38 shows that of the study patients n=325 test results, n=179 (55.1 %) correctly interpreted n=58 (17.8%) incorrectly interpreted and n= 88 (27.1 %) were not interpreted by the registered nurses.

A statistically significant difference was identified (p=0.01) by applying the Pearson Chi-square test between the public and private healthcare sectors concerning the interpretation of tests.

The public healthcare sector through the registered nurses was more likely to interpret the diagnostic tests correctly.

Table 6.38: Test results interpreted (N=325)

Test results interpreted	Public	Private	Total
Correctly interpreted	n=138 (68.0 %)	n=41(33.6 %)	n=179 (55.1 %)
Incorrectly interpreted	n=46 (22.7 %)	n=12 (9.8 %)	n=58 (17.8 %)
Not interpreted	n=19 (9.4 %)	n=69 (56.6 %)	n=88 (27.1 %)
Total	**n=203 (100.0 %)**	**N=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.10 Question 26: Patients 'results reported to the doctor (N=325)

Table 6.39 shows that of the n=325 study patients test results, n=225 (69.2 %) of the patients' tests were reported to the doctor and n=100 (30.8%) were not reported to the doctor. A statistically significant difference (p=0.01) was identified when applying the Pearson Chi-Square test between public and private healthcare sectors concerning test results reported to the doctor.

Test results were more likely to be reported in the public healthcare sector to the doctor while in the private healthcare sector less likely to be reported to the doctor.

Table 6.39: Test results reported to the doctor (N=325)

Test results reported to the doctor	Public	Private	Total
Yes	n=167 (82.3 %)	n=58 (47.5 %)	n=225 (69.2 %)
No	n=36 (17.7 %)	n=64 (52.5 %)	n=100 (30.8 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.11 Question 27: Action taken based on diagnostic tests (N=325)

Table 6.40 shows that in n=169 (52.0%) study patients action was taken on diagnostic test results but n=92 (28.3%) had no action taken. A statistically significant difference was identified (p=0.01)

applying the Pearson Chi-square test between public and private healthcare sectors concerning taking action on diagnostic test results.

The public healthcare sector was more likely to take action based on diagnostic test results.

Table 6.40: Action taken based on the diagnostic test results (N=325)

Action is taken based on the diagnostic test results	Public	Private	Total
Yes	n=133 (65.5 %)	n=36 (29.9 %)	n=169 (52.0 %)
No	n=65 (32.0 %)	n=27 (22.1 %)	n=92 (28.3 %)
99 (not applicable)	n=5 (2.5 %)	n=59 (48.4 %)	n=64 (19.7 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.12 Question 28: Preoperative assessment for surgery (N=325)

As shown in Table 6.41 n=197 study patients required preoperative assessments of which n=48 (14.8%) assessment was done completely, n=110 (33.8%) were not done, and n=39 (12.0%) were done incompletely. The Pearson Chi-square test was applied, and a statistically significant difference was identified between the public and private healthcare sectors concerning the pre-operative assessment for surgery (p=0.01).

The public healthcare sector was more unlikely to do a pre-operative assessment.

Table 6.41: Pre-operative assessment (N=325)

Pre-operative assessment	Public	Private	Total
Complete	n=25 (12.3 %)	n=23 (18.9 %)	n=48 (14.8 %)
Incomplete	n=22 (10.8 %)	n=17 (13.9 %)	n=39 (12.0 %)
Not Done	n=101 (49.8 %)	n=9 (7.4%)	n=110 (33.8 %)
99 (not applicable)	n=55 (27.1 %)	n=73 (59.8 %)	n=128 (39.4 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0%)**	**N=325 (100.0 %)**

6.5.6.13 Question 29: The treatment/technique/management given as prescribed (N=325)

Table 6.42 indicates that of the n=325 study patients requiring treatment/technique/management n= 123 (38.1) study patients received the treatment or technique or management requirements as prescribed, while n=197 (60.6%) were not given.

The Pearson Chi-square test was applied, and no statistically significant differences were identified between the public and private healthcare sectors concerning treatment or technique or management given as prescribed (p=0.207).

Table 6.42. Treatment /technique/management given as prescribed (N=325)

Treatment is given as prescribed	Public	Private	Total
Yes	n=70 (34.5 %)	n=53 (43.4 %)	n=123 (38.1)
No	n=130 (64.0 %)	n=67 (54.9 %)	n=197(60.6)
99 (not applicable)	n=3 (1.5 %)	n=2 (1.6 %)	n=5 (1.5)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0)**

6.5.6.14 Question 30: Patient's reports (initial, progress, interim and discharge reports)

6.5.6.14.1 Initial reports (N=325)

Table 6.43 shows that of the initial n=325 reports, n=155 (47.7 %) were incomplete, n=160 (49.2%) complete and n=10 (3.1%) were not done at all.

A statistical significant difference was identified between the public and private healthcare sectors concerning the initial reports (p=0.01) by applying the Pearson Chi-square test.

The test revealed that the initial reports were more likely to be incomplete in the public healthcare sector.

Table 6.43: Initial reports (N=325)

Initial reports	Public	Private	Total
Complete	n=65 (32.0 %)	n=95 (77.9 %)	n=160 (49.2 %)
Incomplete	n=133 (65.5 %)	n=22 (18.0 %)	n=155 (47. 5 %) (p=0.01)
Not Done	n=5 (2.5 %)	n=5(4.1 %)	n=10 (3.1 %)
Total	**n=203(100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.14.2 Progress reports (N=325)

Table 6.44 show that of the n=325 study patients' progress reports, n=229 (70.5%) were incomplete, n=79 (24, 3%) were complete and n=17(5.2%) not done.

A statistically significant difference was identified when the Pearson chi-square test was applied (p=0.01) between the public and private healthcare sectors concerning progress reports.

In the public healthcare sector, progress reports were more likely to be incomplete.

Table 6.44: Progress reports (N=325)

Progress reports	Public	Private	Total
Complete	n=29 (14.3 %)	n=50 (41.0 %)	n=79 (24.3 %)
Incomplete	n=169 (83.3 %)	n=60 (49.2 %)	n=229 (70.5 %)
Not Done	n=5 (2.5 %)	n=12 (9.8 %)	n=17 (5.2 %)
Total	**n=203(100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.14.3 Correct interpretation of the clinical manifestation reports (N=325)

Table 6.45 shows that the correct interpretation of clinical manifestation reports were incomplete n=240 (73.8%), n=56 (17.2%) were complete, and n=29(8.9%) not done.

Applying the Pearson Chi-square test, a significant statistical difference (p=0.01) was identified between the private and public healthcare sectors concerning the correct interpretation of the clinical manifestation reports.

The correct interpretation of the clinical manifestation reports was more likely to be incomplete in the public sector.

Table 6.45: Correct interpretation of clinical manifestation reports (N=325)

Correct interpretation of clinical manifestation reports	Public	Private	Total
Complete	n=34 (16.7 %)	n=22 (18.0 %)	n=56(17.2 %)
Incomplete	n=163 (80.3 %)	n=77 (63.1 %)	n=240 (73.8 %)
Not Done	n=6 (3.0 %)	n=23 (18.9 %)	n=29(8.9 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.14.4 Interim reports (N=325)

Table 6.46 shows that of the n=325 study patient interim reports, n=229 (70.5%) were in complete, n=79(24.3 %) complete and n=17 (5.2%) were not done. A statistically significant difference (p=0.01) was identified by applying the Pearson Chi-square test between the private and public healthcare sectors concerning interim reports. Interim reports were more likely to be incomplete in the public healthcare sector facilities.

Table 6.46: Interim reports (N=325)

Interim Reports	Public	Private	Total
Complete	n=29 (14.3 %)	n=50 (41.0 %)	n=79 (24.3%)
Incomplete	n=169 (83.3%)	n=60 (49.2 %)	n=229 (70.5 %)

Not Done	n=5 (2.5 %)	n=12 (9.8%)	n=17 (5.2 %)
Total	**n=203(100.0 %)**	**n= 122 (100.0%)**	**N=325 (100.0 %)**

6.5.6.14.5 Reports to the doctor (N=325)

Table 6.47 shows of the n=325 reports to the doctor, n=201 (61.8%) reports to the doctor were incomplete, n=83 (25.5 %) was complete and n=41 (12.6%) were not done.

A statistical significant difference was identified (p=0.01) by applying the Pearson Chi square test between the private and public healthcare sectors concerning reports to the doctor.

Reports to the doctor were more likely to be incomplete in the public healthcare sector.

Table 6.47: Reports to the doctor (N=325)

Reports to the doctor	Public	Private	Total
Complete	n=34 (16.7 %)	n=49(40.2 %)	n=83 (25.5 %)
Incomplete	n=153 (75.4 %)	n=48 (39.3 %)	n=201 (61.8 %)
Not Done	n=16 (7.9 %)	n=25 (20.5 %)	n=41 (12.6%)
Total	**n=203 (100.0 %)**	**n=122 (100.0%)**	**N=325 (100.0 %)**

6.5.6.14.6 Discharge reports (N=325)

Table 6.48 shows that of n=325 discharge reports, the majority of discharge reports n=204 (62.8%) were not done, n=95 (29.2%) were incomplete and n=26 (8.0%) were complete.

A statistically significant difference was identified (p=0.01) by applying the Pearson Chi square test between the private and public healthcare sectors concerning discharge reports. Discharge reports were more likely not done in the private healthcare sector.

Table 6.48: Discharge Reports (N=325)

Discharge Reports	Public	Private	Total
Complete	n=21 (10.3 %)	n=5 (4.1 %)	n=26 (8.0 %)
Incomplete	n=80 (39.4 %)	n=15 (12.3 %)	n=95 (29.2%)
Not Done	n=102 (50.2 %)	n=102 (83.6 %)	n=204 (62.8 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.5.6.15 Question 31: Patient Education given on discharge (N=325)

The majority of patients n=272 (83.7%) did not receive health education on discharge as shown in table 6.49. A statistical significant difference was identified (p=0.01) by applying the Pearson Chi square test between the private and public healthcare sectors with reference to patient education.

Patient education was more likely not done in the private healthcare sector.

Table 6.49: Patient education given on discharge (N=325)

Patient education reports	Public	Private	Total
Yes	n=45 (22.2%)	n=8 (6.6%)	n=53 (16.3%)
No	n=158 (77.8%)	n=114 (93.4%)	n=272 (83.7%)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.6 SECTION D: OPERATING ROOM (QUESTION 32)

This section was to determine whether adverse events in the operating room were as a result of protocols not adhered to.

6.6.1 Question 32: Operating room protocols adhered to (N=325)

Table 6.50 shows that many operating room protocols were not adhered to. Swab count (67.3 %), infection control n=70 (66 %), surgical pause n= 86 (81.9) and use of diathermia n=107 (67.3 %). Statistical significant difference was identified (p=0.01) applying the Pearson Chi-square test between the private and public healthcare sectors concerning adherence to operating room protocols.

The public sector is more likely not to adhere to protocols.

Table 6.50: Protocols followed in the operating theatre

Protocols adhered to in the operating theatre	Yes		Total	No		Total
	Public	**Private**	**Total**	**Public**	**Private**	**Total**
Counting Swab N=104	n=7 (10.4 %)	n=27 (22.1 %)	n=34 (32.7%)	n=60 (89.6 %)	n=10 (8.2 %)	**n=70 (67.3 %)**
Infection control N=106	n=6 (8.9%)	n=30 (24.6%)	n=36 (34%)	n=61 (91%)	n=9 (7.4 %)	n=70 (66 %)
Managing instruments N=106	n=10 (14.9 %)	n=35 (28.7%)	n=45 (42.5 %)	n=57 (85.1%)	n=4 (3.3 %)	n=61 (57.5 %)
Managing specimen N=99	n=6 (9.1%)	n=27 (22.1%)	n=33 (33.3%)	n=60 (90.9%)	n=6 (4.9 %)	n=66 (66.7 %)
Use of diathermia N=107	n=5 (7.3%)	n=30 (24.6 %)	n=35 (32.7%)	n=63 (93.6%)*	n=9 (7.4 %)	n=72 (67.3 %)
Surgical pause or time out N=105	n=5 (7.6%)	n=14 (11.5%)	n=19 (18.1 %)	n=61 (92.4%)	n=25 (20.5 %)	n=86 (81.9 %)*

6.7 SECTION E: ADVERSE EVENTS (QUESTIONS 33-37)

In this section, more than one answer was possible. This section describes the adverse event concerning where the event occurred, and the healthcare professionals involved.

6.7.1 Question 33: The environment where the adverse event occurred (N=325)

Of the 325 patient studies who had an adverse event or more in this study, the majority occurred in the labour ward, n=159(51.1%), n=38 (11.7%) in general wards, n=30 (9.2%) in casualty, n=24 (7.4 %) in the operating theatre and n=22 (6.8 %) in ICU. A statistically significant difference was identified between the private and public healthcare sectors concerning the environment where the adverse events occurred by applying the Pearson Chi-square test (p=0.01).

Patients were more likely to develop an adverse event in the labour ward in the public healthcare sector.

Statistical differences were also identified between the private and public healthcare concerning general wards (p=0.01), neonatal units (p= 0.003) and ICU (p= 0.01). In these environments, the patients were more likely to develop an adverse event in the private healthcare. No statistical differences were identified between private and public health sectors concerning casualty (p=0.402), paediatrics (p=0.072) and theatre environments (p=0.260).

Table 6.51: Environment where the adverse event occurred (N=325)

The environment where the adverse event occurred	Public	Private	Total
General Ward	n=9 (4.4%)	n=29(23.8 %)	n=38(11.7 %)
ICU	n=0 (0.0 %)	n=22 (18.0 %)	n=22 (6.8 %)
Operating room Theatre	n=17(8.4%)	n=7 (5.7 %)	=24 (7.4%)
Orthopaedic	n=4 (2.0 %)	n=7 (5.7 %)	n=11 (3.4 %)
Paediatric Ward	n=3 (1.5 %)	n=6 (4.9 %)	n=9 (2.8 %)
Neonatology Unit	n=3 (1.5 %)	n=10 (8.2 %)	n=13 (4.0 %)
Casualty/ Trauma	n=18 (8.9%)	n=15 (12.3 %)	n=33 (9.2)
Labour	n=143 (70.4 %)	n=15 (12.3 %)	n=158 (48.6%)
Psych	n=0 (0.0 %)	n=1(0.8 %)	n=1 (0.3 %)
Antenatal	n=3(1.5%)	n=10(8.2 %)	n=13 (4.0%)
Post-natal ward	n=2 (0.9%)	n=0(0.0%)	n= 2 (0.6)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.7.2 Question 34: Brief description of the adverse event (N=325)

The adverse events were grouped according to the disciplines.

An overview of the adverse events that occurred in the private and public healthcare sectors are briefly described. The description of adverse events that occurred in the public sector is described in paragraph 5.3.5.2.

6.7.2.1 Midwifery departments

6.7.2.1.1 Overview

The majority of the patients' adverse in the study occurred in labour wards which included n=159 (51.1%) study patients and their babies.

A total of n=139 babies developed cerebral palsy, two from the private sector and n=137 from the public sector.

The trail bundles audited in the study indicated that the cerebral palsy was due to poor monitoring during labour and failure to respond to clinical manifestations.

Five maternity study patients' adverse events resulted in 3 fresh stillborn and 2 maternal deaths in public healthcare sector.

There were no adverse events in the private sector leading to deaths in midwifery departments.

6.7.2.2 In non-midwifery related adverse events

6.7.2.2.1 Overview

The majority of non-midwifery adverse events occurred in general wards n=38 (11.7%). (See table 6.51).

The trial bundles audited in the study indicated that the adverse events were due to incorrect treatment given, delay in giving treatment and poor monitoring.

Non-midwifery adverse events occurred in both the public and private sectors and included injury due to patient falling, n=24 (7.4%) of adverse events due to swabs left inside the patient during surgery, with most occurring in the public sector.

6.7.3 Question 35: Patient outcome(s) as a result of the adverse event. (N=325)

Table 6.52 shows the outcomes of adverse events, what the study patients experienced.

Eighty five (26.2%) required additional surgery. A statistical significant difference was identified between public and private healthcare sectors concerning additional surgery applying the Pearson Chi-Square test (p=0.01) with more study patients likely to have received additional surgery in the private health care sector.

Twenty nine patents died (8.9%). Applying the Pearson Chi-Square test a statistical significant difference (p=0.01) was identified between public and private healthcare sectors concerning the death of the study patients with more likely to have died in the private healthcare sector.

One hundred and seventy five patients were disabled (53.8%). A statistical significant difference was identified between public and private healthcare sectors concerning patients who became disabled applying the Pearson Chi-Square test (p=0.01). The study patients were more likely to have become disabled in the public health care sector.

Two hundred and thirty two patients (71.4 %) required increased hospital stay. No statistically significant differences (p=0.66) were identified between public and private healthcare sectors concerning increased hospital stay applying the Pearson Chi-Square test.

The quality of life of n=247 (76.0%) patients was affected. Pearson Chi-Square test was applied and a statistical significant difference (p=0.01) was identified between public and private healthcare sectors concerning the quality of life of the study patients. The quality of life of patients in the public health care sector were more likely to have been affected.

Table 6.52: The outcomes of the adverse events (N=325)

The outcomes of the adverse events	Public	Private	Total
Additional surgery	n=32 (15.8 %)	n=53 (43.4 %)	n=85 (26.2%)
Death	n=4 (2.0 %)	n=25 (20.5 %)	n=29 (8.9%)
Disabled	n=144 (70.9 %)	n=n=31 (25.4 %)	n=175 (53.8 %)
Increased hospital stay	n=136 (67.0 %)	n=96 (78.7 %)	n=232 (71.4 %)
Quality of life affected	n=163 (80.3 %)	n=84 (68.9 %)	n=247 (76.0%)

6.7.4 Question 36: Healthcare professional (s) or non-healthcare Professionals responsible for adverse events (N=325)

Table 6.53 shows the categories of staff implicated in adverse events affecting n=325 study patients. A Pearson Chi square test was applied and a statistical difference (p=0.01) was found to exist between the private and public healthcare sectors concerning healthcare professional(s) and non-healthcare professionals implicated in adverse events that the study patients suffered.

Medical and nursing staff together were implicated in n=197 (60.6 %) adverse events which were found to be more likely to have occurred in the public health sector

Nursing staff were implicated in n=81 (25%) of the adverse events that study patients experienced which were more likely to be in the private sector.

Medical staff were implicated in n=30 (9.2%) of the adverse events that study patients experienced which were more likely to be in the private sector.

Table 6.53: Healthcare professional (s) or non-healthcare Professionals responsible for adverse events (N=325)

Responsible person	Public	Private	Total
Nursing	n=29 (14.4 %)	n=52 (42.6 %)	n=81 (24.9%)
Medical	n=15 (7.4%)	n=15 (12.3 %)	n=30 (9.2 %)
Both Nursing and Medical	n=144(70.9 %)	n=53 (43.4 %)	n=197 (60.6 %)
Non-healthcare professional	n=7 (3.5 %)	n=0 (0.0 %)	n=7 (2.2 %)
Both Nursing and Non-health care professional	n=6 (3.0 %)	n=2 (1.6 %)	n=8 (2.5 %)
Other	n=2 (1.0 %)	n=0 (0.0 %)	n=2 (0.6 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 5)**

6.7.6 Question 37: Nurse category (ies) involved in the adverse event (N=325)

The midwives were the group mostly involved in adverse events n=164 (43.4%), followed by professional nurses n=128 (33.9%), enrolled nurses n=51 (13.5%) and enrolled nursing assistant n=35 (9.3%).

A statistically significant difference was identified between the public and private health sectors with reference to nurse categories involved in adverse events (p=0.01) applying the Pearson Chi square test.

The public healthcare sector was more likely to have midwives involved in the occurrence of adverse events.

In the private healthcare sector, the professional nurse together with the enrolled and enrolled assistant nurses were more likely to be involved in adverse events.

Table 6.54: Category involved (N=378)

Category involved	Public	Private	Total
Professional Nurse	n=22(12.4 %)	n=106 (52.7 %)	n=128 (33.9 %)
Enrolled Nurse	n=4 (2.3 %)	n=47 (23.4 %)	n=51 (13.5 %)
Enrolled nursing assistant	n=2 (1.1 %)	n=33 (16.4 %)	n=35 (9.3%)
Midwife	n=149 (84.2 %)	n=15 (7.5%)	n=164 (43.4 %)
Total	**n=177 (96.0%)**	**n=201 (53.2%)**	**N=378 (100.0%)**

6.8 SECTION F: PRINCIPAL INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT (QUESTIONS 38-39)

This section refers to the principal incident type, the severity of adverse events and factors contributing to the adverse events.

6.8.1 Question 38: The adverse event by Principal Incident type (N=325)

Clinical management of patients was the most common principal incident type n=291 (89.5%) which contributed to adverse events, followed by human behaviour n=98 (30.2%), organisational n=77 (23.7%) and administrative n=21 (6.5 %) as shown in table 6.56. Statistically significant differences were identified by applying the Pearson Chi-square test between the public and private healthcare sectors concerning the incident type, specifically behaviour (p=0.01) organization (p=0.01) and administration (p=0.01).

The private healthcare sector was more likely to have adverse events occurred due to human behaviour problems, organisational and administrative. In addition, a Pearson statistical significance of (p= 0.27) was identified showing no difference between the private and public healthcare sectors with reference to the clinical management of patients.

Table 6.55: Adverse event by principal type (N=325)

Adverse event by principal type	Public	Private	Total
Clinical management	n=178 (87.7 %)	n=113 (92.6 %)	n=291(89.5 %)
Human behaviour problems	n=25 (12.3 %)	n=73(59.8 %)	n=98 (30.2 %)
Organisational	n=28 (13.8 %)	n=49(40.2 %)	n=77 (23.7 %)
Administrative	n=5 (4.9 %)	n=16 (13.1 %)	n=21 (6.5 %)
Total	**236 (100.0)**	**251 (100.0)**	**N=487 (100.0)**

6.8.2 Question 39: Severity of the adverse event according to the Safety Assessment Code (SAC) Matrix (SA Health Risk Management Framework, nd). (N=325)

Table 6.56 shows that the majority of the adverse events were extreme n=228 (70.2 %). Fifty six (17.2 %) adverse events were major and n=33 (10.2 %) were moderate. The Pearson Chi square test identified a statistically significant difference (p=0.01) between public and private healthcare sectors concerning the severity of adverse events.

Extreme adverse events are more likely to occur in the public healthcare sector, major, moderate and minor more likely to occur in the private sector.

Table 6.56: Severity of adverse events using the SAC (N=325)

Adverse event by principal type	Public	Private	Total
Extreme	n=180 (88.7 %)	n=48 (39.3 %)	n=228 (70.2%)
Major	n=22 (10.8) %	n=34 (27.9%)	n=56 (17.2 %)
Moderate	n=1 (0.5 %)	n=32 (26.2 %)	n=33 (10.2 %)
Minor	n=0 (0.0 %)	n=7 (5.7 %)	n=7 (2.2 %)
Insignificant	n=0 (0.0 %)	n=1 (0.8 %)	n=1 (0.3 %)
Total	**n=203 (100.0 %)**	**n=122 (100.0 %)**	**N=325 (100.0 %)**

6.8.3 Question 40: Factors contributing to the adverse event (N=325)

Table 6.57 shows that there were various contributing factors that contributed to the adverse events resulting in medical malpractice litigation in Nursing Practice in South Africa as shown through the audit of N= 325 trial bundles.

Contributing factors included:

- Failing to apply guidelines / protocols n= 297 (91.4 %) is the leading factor contributing to an adverse event,
- poor monitoring n=240 (73.8 %),
- clinical manifestations not responded to, n=238(73.2 %) and
- accumulation of errors n=136 (41.8 %).

A Pearson Chi square test was applied, and statistical differences were identified between private and public healthcare sectors with specific reference to the following:

-
- failing to give treatment (p=0.01)
- incorrect treatment (p=0.01)
- lack of knowledge (p=0.01)
- lack of training (p=0.01)
- behavioural (p=0.01)
- system failure (p=0.01)
- not responding to clinical manifestations (p=0.001) and
- accumulation of errors (p=0.003).

Adverse events are more likely to occur in the private healthcare sector due to the following:

- lack of knowledge
- lack of training
- lack of supervision(p=0.01)

- behaviour (p=0.01)
- system failure (p=0.01)
- incorrect treatment (p=0.01)
- failing to give treatment and (p=0.01)
- accumulation of errors. (p=0.38)

In the public healthcare sector, adverse events are more likely to occur due to not responding to clinical manifestations. No statistical differences were identified between private and public healthcare sectors with reference to failing to apply guidelines (0.84) and accumulation of omissions (0.38).

Table 6.57: Contributing factors to adverse events

Contributing factors to adverse events	Public	Private	Total
Clinical manifestation not responded to	n=161 (79.3 %)	n=77(63.1 %)	n=238(73.2 %)
Poor monitoring	n=156 (76.8 %)	n=84 (68.9 %)	n=240 (73.8 %)
Failing to apply guidelines / protocols	n=186 (91.6 %)	n=111 (91.0 %)	n=297 (91.4 %)
Failing to give treatment as required	n=81 (39.9 %)	n=81 (66.4 %)	n=162 (49.8 %)
Incorrect Treatment	n=20 (9.9 %)	n=32 (26.2 %)	n=52 (16.0 %)
Accumulation of omissions	n=105 (51.7%)	n=57 (46.7 %)	n=162 (49.8 %)
Accumulation of errors	n=72 (35.5 %)	n=64 (52.5 %)	n=136 (41.8 %)
System failure	n=25 (12.3 %)	n=45 (36.9 %)	n=70 (21.5 %)
Behavioural e.g. attitude	n=6 (3.0 %)	n=80 (65.6 %)	n=86 (26.5 %)
Lack of supervision	n=2 (1.0)	n=55 (45.1 %)	n=57 (17.5 %)
Lack of training	n=0 (0.0)	n=63 (51.6 %)	n=63 (19.4 %)
Lack of Knowledge	n=2 (1.0)	n=92 (75.4 %)	n=94 (28.9 %)

6.9 SUMMARY

This chapter described a comparative statistical analysis between the private and public healthcare sectors. The data from 122 trial bundles of the private sector was collected in the Western Cape and Gauteng provinces where the largest private hospitals are found as described in chapter 4.

The data from 203 trial bundles of the public healthcare sector was collected in Gauteng and the Eastern Cape provinces due to the highest litigation in healthcare in South Africa (see chapter 4).

Results have shown that there is no statistical difference concerning the clinical management of patients (p=0.27). However, the study results have shown that the private healthcare sector had

completed nursing notes, initial assessments, care plans and special care plans. Vital sign monitoring was also better in the private sector.

Furthermore, the results have shown that most malpractice litigation in public healthcare sector was as a result of midwifery practice in South Africa, most of the adverse events occurred in the labour ward, n=158(48.6%). A total of n=139 babies were born with cerebral palsy due to poor monitoring, two from the private sector and n=137 from the public sector. Adverse events leading to malpractice litigation in nursing practice accounted for 90.1% of maternity-related conditions.

The majority of the patients suffered an adverse event that is extreme n=228 (70.2%) in severity and had their quality of life permanently affected. Statistical differences concerning death (p=0.01, disability (p=0.01), additional surgery (p=0.01), quality of life affected (p=0.01) between private and public healthcare sectors were identified. Patents were more likely to have died in private healthcare and have had additional surgery, while in the public sector patients were more likely to have developed a disability and have their quality of life affected. The results reveal that there is no statistical difference concerning increased hospital stay between private and public healthcare sectors.

6.10 CONCLUSION

The researcher successfully completed a comparative statistical analysis of adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces, an objective of this study. This led to testing the hypotheses:

H_1: There are statistical differences between the public and private analysis of adverse events which led to malpractice litigation in nursing practice **was accepted.**

H_0: There are no statistical differences between the public and private analysis of adverse events which led to malpractice litigation in nursing practice **was rejected.**

Objective 2: To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces was set for this study and successfully addressed in this chapter.

CHAPTER 7: RESULTS OF THE DRAFTED RECOMMENDED GUIDELINES

7.1 OVERVIEW OF THE RESULTS

The results of the drafted recommended guidelines that may contribute to the prevention of malpractice litigation in nursing practice in South Africa are presented in this chapter. The results are described according to round one and two. The criteria set for the consensus Delphi method was set at 80%. Only two guidelines were deleted as the agreement score was below 80% and the participants had a lot of negative comments regarding these draft guidelines. Round two in the Delphi method was conducted as the participants accepted the guidelines but recommended that the guidelines should be rearranged and rephrased. The drafted recommended guidelines are described according to the principal incident types that were associated with adverse events, including the demographic profile of the participants. The principal incident type administrative was incorporated. The following are thus described:

- **Section A:** Demographic profile of participants
- **Section B**: Clinical management
- **Section C**: Human behavioural problem
- **Section D:** Organisation

7.2 THE RESULTS OF ROUND ONE OF THE VALIDATION PROCESS

The researcher presents the results as obtained from round 1. The return rate of N= 82 questionnaires which were sent to experts was N=60 (73.1%). Participants had a choice between agree or disagree when responding to the drafted recommended guidelines.

7.2.1 Section A: Demographic profile of participants N=60

7.2.1.1 Question 1: Professional registration status of participants

Table 7.1 shows that n=57 (95.0%) participants were registered nurses, and only n=3(5.0%) were registered, medical doctors.

Table 7.1: Professional registration status of participants N=60

	Frequency (n) / Percentage %
Registered nurse	n=57 (95.0%)
Register Medical Doctor	n=3 (5.0%)
Total	**N=60 (100%)**

7.2.1.2 Question 2. Highest professional qualification N=60

The majority of the participants had a masters' degree n=45 (75%) and n=15(25%) a doctorate.

Table 7.2: Highest professional qualification N=60

	Frequency (n)/ Percentage
Master's degree	n=45 (75.0%)
Doctorate degree	n=15 (25.0%)
Total	**N=60 (100%)**

7.2.1.3 Question 3: Clinical speciality area N=60

The participants represented most clinical specialities, as shown in table 7.3 with the highest number from midwifery n=25 (41.7%).

Table 7.3: Clinical speciality area N=60

	Frequency=n Percentage %
Medical	n=16 (26.7%)
Midwifery	n=25 (41.7%)
Neonatology	n=10 (16.7%)
Nephrology	n=3 (5.0%)
Neurology	n=1 (1.7%)
Ophthalmology	n=0 (0.0%)
Orthopaedics	n=0 (0.0%)
Paediatrics	n=5 (8.3%)
Psychology	n=0 (0.0%)
Surgical	n=2 (2.2%)
Trauma	n=1 (1.7%)
Urology	n=0 (0.0%)
Public health	n=9 (0.0%)
Obstetrics	n=2 (3.3%)
Other (specify)	n=17 (28.3%)
Not applicable	n=5 (8.3%)

7.2.1.4 Question 4: Participants' area of participation N=60

As shown in table 7.4, the participants were from a variety of healthcare areas. Participants included members of South African Nursing Council, Council for Health Service Accreditation in Southern Africa (COHSASA), Heads of Nursing schools at universities and nursing colleges,

Provincial Department of Health, three international countries, specialists in clinical care and academia. Most participants indicated that they were active in clinical practice n=29 (48.3%), and n=16 (26.7%) were working as academics in healthcare.

Table 7.4: Participants 'area of participation

	Frequency (n) %
Academics in healthcare	n=16 (26.7%)
Consultants in health care systems	n=6 (10.0%)
Participating in the accreditation of hospitals	n=9 (15.0%)
Participating in policymaking in healthcare	n=8 (13.3%)
Participating in regulating bodies in healthcare	n=7 (11.7%)
Writing healthcare standards for health establishments	n=6 (10.0%)
Clinical practice	n=29 (48.3%)
Other	n=7 (11.7%)

7.2.2 Section B. Clinical management: Phases of the nursing process

This section includes the recommended drafted guidelines related to clinical management which include the phases of the nursing process:

7.2.2.1 Question 5: Knowledge and understanding of the Nursing Process N=60

5A. The nurse should have the required knowledge and understanding of the phases of the nursing process, N=60 responded.

1. The knowledge of the phases can be assessed by doing a pre-test and post-test at the beginning of the training. Six participants chose the option to disagree. Fifty-four participants (90%) agreed, but some commented that this recommended drafted guideline needs to be rephrased.

7.2.2.1.1 Nursing process: Phase 1 Assessment

7.2.2.2 Question 6A: Subjective data

The number of participants who responded to this question varied from N=57 to N=60.

The nurse should collect the patient's subjective data (demographic, personal and social data) during the assessment.

Two participants disagreed that the nurse is responsible for collecting data on age and gender; three disagreed with marital status and one on dependents. The participants indicated that information relating to the age of the patient, gender and marital status are collected by the administration staff. The role of the nurse is to verify if the information was collected. All other recommended drafted guidelines in this section were agreed upon (100%).

Table 7.5: Subjective data

Recommended drafted guidelines		Agree
5B. The nurse should collect the patient's subjective data (demographic, personal and social data) during the assessment, namely:		
1.	Age of the patient	N=57 (96.6%)
2.	Gender	N=58 (96.7%)
3.	Marital status	N=57 (95%)
4.	Dependents	N=58 (98.3%)
2..	Disability on admission	N=60 (100%)
3.	Social habits which include:	
3.1	Smoking	N=60 (100%)
3.2	Use of alcohol	N=59 (100%)
3.3	Use of unsolicited drugs	N=60 (100%)
5.B	A comprehensive medical and family history taking should be done of all patients as it stated by the scope of practice for nurses (R2598 of 1984)	N=60 (100%)

7.2.2.3 Question 6B: Subjective

A comprehensive medical and family history taking should be done of all patients as stated in the scope of practice for nurses (R2598 of 1984 as promulgated by the Nursing Act, 1978 (Act No. 50 of 1978) (See table 7.5).

All participants (100 %) agreed to this recommended drafted guideline.

Comments from the participants included: one indicated that the new regulations must be used.

The nurse should have the required knowledge and understanding of the phases of the nursing process. Two (3.3%) of n=60 participants indicated that it is important to indicate the nurse category because not all nurses are allowed to do the nursing process. A second participant indicated that the nurses should have the knowledge to interpret, implement the nursing process and do the record keeping.

7.2.2.4 Question 6: Objective data

The number of participants who responded varied between N= 51 and N=60 as shown in table 7.6.

6A. The nurse should collect the patient's objective data during assessment which include vital signs and other special tests depending on the patient's condition and where applicable.

The majority of participants agreed (100%), as shown in table 7.6 to the recommended drafted guidelines. The participants who disagreed indicated that "where applicable should be added".

One participant commented that the information would be a baseline for detection of abnormalities and provision of safe patient care.

Table 7.6: Objective data

Recommended drafted guidelines	Agree
1. Blood pressure	N=60 (100%)
2. Pulse	N=60 (100%
3.Temperature	N=60 (100%)
4.Respirations	N=60 (100%
5.Foetal heart monitoring	N=60 (100%
6.Foot pulse monitoring	N=58 (96.7%)
7.Continuous ECG monitoring	N=56 (93.3%)
8.Post spinal surgery	N=51 (89.5%)
9.Oxygen saturation	N=60 (100%)
10. Circulation checks post plaster of Paris insertion	N=57 (98.2%)
11. Neuro observations.	N=59 (100%)

7.2.2.5 Question 6B: Special tests which form part of the assessment.

The number of participants who responded varied from N=59 to N=60.

The participant commented that special tests should be referred to as investigations and not tests. Table 7.7 shows that the majority agreed (100% that these tests should be done. However, those who disagreed indicated that not all patients required these tests and that the researcher should add “where applicable”.

Table 7.7: Special tests which form part of the assessment

Recommended drafted guidelines	Results
1.Haemoglobin	N=59 (98.3%)
2. Haemoglucotest	N=60 (100%)
3. Urinalysis	N=60 (100%)
4. Weight	N=60 (100%)
5. Intake and output	N=56 (93.3%)
6. Height	N=59 (100%)

7.2.2.6 Question 6C: Physical assessment and Interpretation of data N=60

The nurse should be able to conduct a physical assessment of the patient, which include:

- **Question 9a:** Examination of the body, head to toe checking for any abnormalities, bruises, discolouration, any disfigurement, pressure sores, and signs of dehydration. One participant indicated that this assessment is not always required for all patients but

relevant to babies, frail elderly and in the case of suspected child abuse. All participants agreed. N=60(100 %).

- **Question 6b**: The specialist nurse should perform heart and lung auscultation. All participants agreed. N=55(98.3%) except one participant who disagreed and indicated that all professional nurses should be able to perform heart and lung auscultation.

7.2.3 Nursing process: Phase 2 Formulating a nursing diagnosis

7.2.3.1 Question 7: Formulating a nursing diagnosis

1. The nurse should be able to analyse all data collected during the assessment phase, interpret it and formulate nursing diagnosis**.** Most participants agreed. N=60(100%) to the drafted guidelines recommended. The majority of participants believed that this recommendation should be clear and accessible to the nurses. One indicated that if appropriate nursing diagnosis is formulated, safe patient care will be promoted. All participants agreed to the various aspects of assessment except for one participant who indicated that the nurse could refer to the laboratory tests as shown in Table 7.8

Table 7.8: Formulating a nursing diagnosis

Recommended drafted guidelines		Agree
The nurse should be able to analyse all data collected during the assessment phase, interpret it and formulate nursing diagnosis.		N=60 (100%)
1.	Should understand and be able to interpret the subjective statements from the patient	N=60 (100%)
2.	Should understand and be able to interpret the patient's mental and emotional status	N=60 (100%)
3.	Should understand and be able to interpret the data obtained from physical assessment	N=60 (100%)
	To formulate the correct nursing diagnosis, the nurse should understand the following:	
1.	Normal and abnormal ranges of the vital signs	N=60 (100%)
2.	Normal and abnormal ranges of the tests that are done on the patients	N=55 (100%)
3.	Data obtained from physical assessment	N=55 (100%)
4.	Normal and abnormal ranges of the special tests done	N=55 (100%)

7.2.4 Nursing process Phase 3: Planning

During this phase, the professional nurse draws up a care plan based on the diagnosis or diagnoses.

7.2.4.1 Question 8: Planning

The responses to planning varied from N=57 to N=60.

As shown in table 7.9, all participants (100%) agreed to the recommended drafted guidelines except for the guideline about the multidisciplinary team. Several negative comments about this guideline were received. Consequently, this guideline is not recommended.

Table 7.9: Nursing Process: Planning

Recommended drafted guidelines	Agree
1. The nurse should understand how to set the nursing interventions and outcomes	N=58 (100%)
2. The nursing care plans should be set so that they are achievable and measurable	N=59 (100%)
3. The multidisciplinary team has to be included during this stage, of which the scope of practice is taken into consideration.	N=57 (96.6%)
4. The nurse should set long and short term goals, and each goal should have an expected outcome.	N=60 (100%)
5. This stage depends on the nursing diagnoses that are formulated, and the patient's needs should be prioritised using Maslow's hierarchy of needs.	N=58 (98.3%)
6. The special care plans are also formulated during this stage to manage patients with special needs such as a woman in labour, a woman who has diabetes and	N=60 (100%)
7. The nursing care plans should be written clearly on the patient's nursing process records so that they are accessible to other health professionals	N=60 (100%)

7.2.5 Nursing process Phase 4: Implementation

During this phase, the care plans formulated in phase 3 are implemented.

7.2.5.1 Question 9: Implementation

Response varied between N=59 and N=60.

All participants (100%) agreed to the recommended drafted guidelines as shown in table 7.10.

Table 7.10: Nursing Process: Implementation

Recommended drafted guidelines	Agree
1. The care plans are implemented in this stage during which a nurse carries out the care plans that were formulated in phase 3.	N=60 (100%)
2. The nurse should conduct nursing care activities, and these should be guided by the availability of skills, knowledge and scope of practice	N=60 (100%)
3. Patient treatment techniques that were prescribed in phase 3 are executed in this stage	N=59 (100%)
4. The nurse should adhere to protocols, guidelines and standards that are laid down by the institution, governing body and employer.	N=60 (100%)

7.2.6 Nursing process: Phase 5: Evaluation

During this phase, the care given to the patient is evaluated.

7.2.6.1 Question 9: Evaluation N=60

All the participants agreed (100%) except for one drafted guideline, which was not accepted by two participants, as shown in table 7.11. The reason given was that the evaluation should be

part of each phase. However, this is a drafted guideline and evaluation is continuous, as shown in table 7.11.

Table 7.11: Nursing Process: Evaluation

Recommended drafted guidelines		Agree
1.	This is a stage where a nurse continuously evaluates the effectiveness of the nursing care activities documented in the implementation and planning stages	N=60 (100%)
2.	The nurse then modifies the care plan as needed	N=60 (100%)
3.	If the patient‘s condition has not improved the scientific nursing process is recommenced from stage 1 to stage 5	N=58 (96.7%)

7.2.7 Documentation

7.2.7.1 Question 10a. Documentation

Documentation should be included as the last phase in the nursing process so that there can be improved documentation of the patient’s information. Six participants disagreed, and n=54 (89.8%) agreed. This guideline is not recommended. Participants indicated that documentation should be done concurrently with all interventions to ensure accuracy and completeness of the record.

Most of the recommended drafted guidelines, as shown in table 7.12, were accepted.

Table 7.12: Documentation

Recommended drafted guidelines		Agree
1.	Documentation should be included as the last phase in the nursing process so that there can be improved documentation of patient’s information.	N=53 (89.8%)
2.	Documentation should meet the acceptable principals of documentation	N=54 (100%)
3.	Clear documentation that is precise to the point	N=58 (100%)
4.	Signature and designation of the person that was documenting should be clear	N=59 (98.3%)
5.	Date and time should always appear in the patient’s records	N=59 (100%)
6.	Correction ink should not be used in patients’ documents	N=60 (100%)

7.2.7.2 Question 10b: Patient Reports

Most participants (100%) agreed to the recommended drafted guidelines, as shown in table 7.13. Comments about discharge reports included that critical information such as reasons for returning to the health establishment or when to seek medical help should be documented.

Discharge reports should indicate what patient education should be given; however, one of the participants indicated that the researcher should be specific on what needs to be covered under patient education. The participant further explained that there is always an oversight on the follow- up and referrals. The participant suggested that the emphasis should be mainly on the

medication component. Another participant suggested that the recommendation should include patient and family health education. Fifty-nine (98.7%) participants agreed, and 1 disagreed.

Table 7.13: Patient reports

Recommended drafted guidelines		Agree
10B. The patient's report should be written completely, which follows the stages of the nursing process:		
1.	Initial report	N=60 (100%)
2.	Progress reports	N=60 (100%)
3.	Interim reports	N=60 (100%)
4.	Transfer reports	N=60 (100%)
5.	Crisis report	N=60 (100%)
6.	Death report	N=59 (100%)
7.	Discharge reports	N=60 (100%
8.	Discharge reports should indicate patient education given	N=59 (98.3%)

7.2.8 Section C: Human behaviour

7.2.8.1 Question 11: Behavioural problems

The number of responses varied from N=56 to N=59.

The health care professionals' behavioural problems may be addressed by nursing management as shown in table 7.14.

The majority of the participants, as shown in table 7.14, have agreed to the recommended drafted guidelines except for three participants who required greater clarity.

Table 7.14: Human behavioural problems

Recommended drafted guidelines	Agree
Question 11. Health care professionals' behavioural problems may be addressed by nursing management as follows:	
1. Ensuring that a HE nursing philosophy is in place which is discussed periodically for reinforcement	N=59 (100%)
2. Encouragement of good moral behaviour amongst the nurses	N=59 (100%)
3. Positive behaviour amongst HE managers may result in quality care being delivered, reduced patient complaints and satisfied patients	N=57 (98.3%)
4. Ensuring that there is openness, transparency, honesty, professional values amongst the health care professionals in the HE	N=59 (100%)
5. Ensuring that there is continuous staff motivation so that staff demotivation is reduced	N=59 (100%)
6. Introduction of a just culture environment in the HE to promote the need for an open and honest reporting system within a quality learning environment.	N=59 (100%)
7. Attending to the factors that can negatively affect the staff behaviours such as staff shortage, work overload, favouritism, compulsory overtime, conflicts	N=59 (100%)
8. Introduce an environment that is non-punitive but corrective	N=58 (100%)
9. Implementing a 'just culture' in event management, the contributing organisational and environmental factors are identified, as well as the nurses' responsibility and accountability	N=58 (100%)
10. A culture of trust, reporting, transparency and discipline are needed for the delivery of safe, quality patient care	N=60 (100%)
11. Introduce and implement disciplinary measures where it is necessary.	N=59 (100%)
12. Introduce a grievance procedure	N=58 (100%)
13. Introduce a performance appraisal programme to award the best performing staff members	N=59 (100%)
14. Establishment and strengthening debriefing centres in the HE such as staff counselling centres, Employee Assistant Programmes, clinical psychology and team building committees	N=58 (100%)
15. Conduct climate meetings whereby each staff member will feel free to voice without fear, concerns without fear of discrimination and victimisation	N=58 (100%)
16. Establish a strengthened relationship with relevant stakeholders	N=56 (98.3%)
17. Establish a good relationship between Nursing education institutions and hospitals. The relationship will assist with standardisation of nursing practices and assist the when mentoring nursing students and team building.	N=58 (98.3%)

7.2.9 Section D. Organisational factors

In this section, the recommended drafted guidelines on organisational factors include:

- Nursing leadership and management
- Mentoring and coaching
- Operational management
- Continued nursing professional development (CPD)
- Nursing monitoring and evaluation.

7.2.9.1 Question 12a Nursing leadership and management

The number of participants who responded to this question varied from N=58 and N=60, as shown in table 7.15.

The HE should ensure the establishment of effective leadership, active collaboration and good governance. A participant suggested that quality care that is informed by good governance, effective management of resources, i.e. material and human, and finances, should be ensured. N=60 (100%) agreed with this drafted guideline.

Only two recommended drafted guidelines, as shown in table 7.15 obtained a result of 98.3%; all other drafted guidelines were 100%.

Table 7.15: Nursing leadership and management

Recommended drafted guidelines		Agree
12A.	The HE should establish effective leadership, active collaboration and good governance by:	N=60 (100%)
1.	Ensuring that quality assurance department and in-service education departments work together to identify and address the knowledge gaps	N=60 (100%)
2.	Establishment of committees for quality assurance committee, research committee, in-service education committees, budgets, health and safety, skills development and auditing and each department should be represented	N=60 (100%
3.	Ensuring that the committees are resourced and functional	N=60 (100%)
4.	Proper planning and organisation which in HE can contribute to the prevention of the provision of substandard care.	N=60 (100%)
5.	Development of strategic plans, institutional year plans, unit year plans that will guide the nursing care activities.	N=59 (100%)
6.	Ensuring that there are proper staffing norms and the staff is allocated according to the needs of each department	N=59 (100%)
7.	Ensuring that budgeting is in line with the Public Finance Management Act and the needs of the clinical area.	N=60 (100%)
8.	Prioritising adequate human and material resources	N=60 (100%)
9.	Ensuring that budget allocation is sufficient to appoint new staff members to overcome staff shortages that may lead to adverse events	N=59 (100%)
10.	Employment of effective recruitment and retention strategies.	N=60 (100%)
11.	Budget allocation for staff development.	N=60 (100%)
12.	Establishment of cost containment committees that will ensure proper financial management and attending to priority needs of the HE.	N=59(100%)
13.	Development and implementation of structure standards, process standards and outcome standards	N=60 (100%)
14.	Implementation of the National core standards in the operational plans	N=59 (98.3%)
15.	Implementation of the Bathopele Principals	N=59 (98.3%)
16.	Implement patients' rights charter whereby patients' rights are respected and not violated in the HE.	N=59 (100%)

17.	Ensuring that the vision and mission statement should give guidance to service delivery	N=60 (100%)
18.	Ensuring that there is an infection control department.	N=60 (100%
19.	Ensuring that the disaster management plan is in place	N=60 (100%
20.	Ensuring that a risk management plan should be in place and the staff should be knowledgeable on how to manage, to analyse and assess risk	N=60 (100%
21.	An effective communication system whereby patients and staff members are well informed should be in place	N=59 (100%
22.	Ensuring that the facilities and infrastructure are maintained and well equipped to that they meet the applicable regulations	N=58 (100%)
23.	Establishment of a good relationship between Nursing education institutions and hospitals The relationship will assist with standardisation of nursing practices and assist when mentoring nursing students	N=58 (100%)
24.	Ensuring that community involvement is strengthened by the HE management system	N=58 (100%)
25.	There should be proper selection criteria for staff members before employment especially those that are in management positions	N=59 (100%)
26.	Management skills and styles need to be properly explored to avoid selecting managers who lack management skills as this may lead to poor management and substandard care being provided in HE	N=58 (100%
27.	A multidisciplinary approach should be applied to ensure an efficient and effective HE organisation	N=58 (100%)

7.2.9.2 Question 12b: Mentoring and Coaching.

Responses to this guideline varied from N=57 and N=60. Two of the drafted guidelines had agreed to responses of less than 100%. Comments from the participants included that it would increase competence, decrease job-related anxiety, increase the likelihood of adverse events in advance of them occurring allowing for early intervention. Another participant believed that continuous mentoring and coaching should apply to all nurses as part of their appraisal process and then be used to compile their learning plan for the coming year.

Table 7.16: Mentoring and coaching

	Recommended drafted guidelines	**Agree**
1.	Ensuring increased continuous mentoring and coaching within the work environment will increase job security	N=60 (100%)
2.	Coaching should be done with supervision and be provided in a non-threatening, noninterfering manner	N=60 (100%)
3.	Introduce mentors to couch and support the newly employed nurses, student nurses and those that have been employed for a long time. Each ward/unit should have its mentor that is responsible to mentor the newly appointed staff and students. This will instil confidence and productivity in their work. Besides, this will provide opportunities for staff members to ventilate their feelings and fears	N=57 (96.6%)
4.	Offer induction and orientation for newly appointed staff members at least for the first 2 weeks after an appointment	N=58 (98.3%)
5.	Continuous coaching and supervision will allow the senior nurse practitioner to identify the current level of competency with which duties are executed.	N=60 (100%)

7.2.9.3 Question 12c: Operational management

All participants (100%) agreed to the recommended drafted guidelines about the wards/units in HE to ensure the implementation of HE operational plans.

Table 7.17: Operational management

Recommended drafted guidelines		Agree
12.C. Operational management: The wards/units in HE should reflect the implementation of HE operational plans and can be done by ensuring that:		
1.	Institutional plans are implemented, and the unit operational plans are in line with those of the HE	N=60 (100%)
2.	There is enough supply of equipment, and that these are in good working condition	N=60 (100%)
3.	The measures to control infection are in place, and the staff is well informed about these measures	N=60 (100%)
4.	Ensure that stock supply and control is done	N=59 (100%)
5.	Treatment techniques are implemented	N=58 (100%)
6.	There is unit team building	N=59 (100%)
7.	There is staff development	N=59 (100%)
8.	Proper organisation and planning	N=59 (100%)
9.	There are proper work allocation and distribution of work according to the scope of practice	N=58 (100%)
10.	Patient safety measures are in place such as infection control measures and cleanliness.	N=60 (100%)
11.	The operational standards are implemented guided by guidelines, policies, acts and regulations	N=60 (100%)
12.	Management by objectives, in-service training and clinical demonstrations can be used as unit/ ward measures for staff development	N=60 (100%)
13.	Risk management, disaster management are in place	N=59 (100%)
14.	Conflict management is in place	N=58 (100%)

7.2.9.4 Question 12d: Continuing nursing professional development

The responses to the recommended drafted guidelines regarding professional development varied from N=58 to N=60, as shown in table 7.18. Most participants agreed (100%) to these recommended drafted guidelines. The participants suggested that the Refresher Course of at least six months in the Health Establishment should depend on the needs of the Health Establishment.

Table 7.18: Continuous nursing professional development

Recommended drafted guidelines		Agree
1.	Identify knowledge gaps in each HE by conducting small surveys and clinical audits	N=59 (98.3%)
2.	Encourage staff members to identify the areas they do not feel competent in	N=59 (100%)
3.	Introduce a scheduled programme for in-service and informal training at the hospital level.	N=59 (100%)
4.	Identify topics that will be offered every week and those that will be offered on 6 months' basis	N=58 (100%)
5.	Informal training can be implemented by making use of the morning meeting session, using posters and pictures to engage all learning strategies	N=60 (100%)
6.	Prioritise the topics that have to be included in the HE in-service education programme based on the identified needs	N=60 (100%)
7.	Send staff members to seminars, conferences and workshops	N=59 (100%)
8.	Encourage staff members to register for formal education at colleges and universities.	N=60 (100%)
9.	Incorporation of adverse events and malpractice litigation in Nursing Education Institutions curricula	N=59 (98.3%)
10.	Identified knowledge gaps should be bridged by doing refresher courses	N=59 (100%)
11.	In-service education department should ensure implementation of the in-service education programmes. Management by objective, clinical demonstrations	N=60 (100%)
12.	Refresher course at least six months in the Health Establishment on the following:	N=60 (100%)
1.	Anatomy and physiology	N=59 (98.3%)
2.	Pathophysiology of the most common diseases	N=59 (98.3%)
3.	Management of pathological conditions	N=60 (100%)
4.	Medication indication, contraindications, side effects, effects, action, route and dosage	N=58 (98.3%)
5.	Control of drugs	N=59 (98.3%)
6.	Establish opportunities where nursing personnel can be made aware of the adverse events as well as the near misses within the organisation and how these gaps are negatively affecting the quality and safety of patient care. The nurses should be given in-service education on how to analyse the adverse events and write reports on this. The preventive measures on adverse events are to be taught as well.	N=58 (100%)

7.2.9.5 Question 12e Nursing monitoring and evaluation: Clinical audits

The response rate varied from N=58 to N=60.

Most participants agreed (100%) to the recommended drafted guidelines, as shown in

Table 7.19. Comments from participants suggested that other more comprehensive methods should be employed for the identification of knowledge gaps as well. "Audits tend to be pretty narrowly focussed, as required for successful audit outcomes".

Table 7.19: Nursing monitoring and evaluation: Clinical audits

Recommended drafted guidelines		Agree
Conduct clinical audits and check if the following are carried out as per guidelines, policies and regulations:		N=60 (100%)
1.	Patients' assessment guided by the nursing process phases	N=60 (100%)
2.	Patients' reports if these are complete	N=58 (98.3%)
3.	Management and treatment techniques	N=58 (98.3%)
4.	Organisational, planning and implementation of guidelines	N=59 (100%)
5.	Supervision, mentoring and training of staff	N=60 (100%)
6.	Reporting and assessment of the adverse events	N=59 (100%)
7.	Strengthen patient satisfaction surveys	N=58 (100%)
8.	Ensure there is a system to redress the challenges identified in the surveys and clinical audits	N=60 (100%)
9.	Quality improvement projects should be in place so that the problems identified during auditing are addressed	N=60 (100%)
10.	Measures to redress the complaints are to be in place and accessible to patients	N=59 (100%)

7.3 RESULTS OF ROUND TWO OF THE VALIDATION PROCESS

7.3.1 Overview of the results

Sixty questionnaires were sent out to the participants who participated in round 1, with a return rate of n=36(60%). The results of n=36 experts participated in round two. The participants in some areas suggested that the guidelines should be rephrased.

7.3.2 Section A: Demographic profile of Delphi participant

7.3.2.1 Question 1: Professional category N=36

One registered medical doctor participated in round two and n=35 were registered nurses.

Table 7.20: Professional category N=36

	Frequency (n) Percentage %
Registered nurses	n=35 (97.2%)
Registered Medical Doctor	n=1 (2.8%)
Total	N=36 (100%)

7.3.2.2 Question 2: Highest professional qualification N=36

The participants that participated in round two had masters' degrees, n=26(72.2%) and n=10 (27.8%) PhD degrees.

Table 7.21: Highest professional qualification N=36

	Frequency (n) Percentage %
Master's degree	n=26 (72.2%)
Doctorate degree	n=10 (27.8%)
Total	**N=36 (100%)**

7.3.2.3 Question 3: Clinical speciality area N=36

The participants had a variety of clinical specialities, as shown in table 7.22 with most participants coming from midwifery n=25 (41.7%), followed by n=15 from medical departments and n=3 in neonatology. Two worked in other departments that included nursing administration, nutrition department or psychiatry. Furthermore, some participants worked in more than one speciality areas and thus had to choose more than one options.

Table 7.22: Clinical speciality area N=36

	Frequency
Medical	n=7 (19.4%)
Midwifery	n=15 (41.7%0
Neonatology	n=3 (8.3%)
Nephrology	n=0 (0.0%)
Neurology	n=1 (2.8%)
Ophthalmology	n=0 (0.0%)
Orthopaedics	n=0 (0.0%)
Paediatrics	n=3 (8.3%
Psychology	n=0 (0.0%)
Surgical	n=3 (8.3%)
Trauma	n=1 (2.8%)
Urology	n=0 (0.0%)
Public health	n=5 (0.0%)
Obstetrics	n=0 (0.0%)
Other (specify)	n=12 (0.0%)
Not applicable	n=2 (5.6%)

7.3.2.4 Question 4: Participants 'area of participation

As shown in table 7.23 the majority of participants were participating in academic health care n=31(86.1%), n=21(58.3%), or were working in clinical practice. A participant could be participating in more than one area and may have chosen more than one option. Participants included members of SANC, COHSASA, Heads of Nursing Schools and Colleges, specialists from the clinical and academic environment.

Table 7.23: Participants' area of participation

	Frequency (n) Percentage %
Academics in healthcare	n=31 (86.1%)
Consultants in health care systems	n=4 (11.1%)
Participating in the accreditation of hospitals	n=5 (13.9%)
Participating in policymaking in healthcare	n=12 (33.3%)
Participating in regulating bodies in healthcare	n=6 (16.7%)
Writing healthcare standards for health establishments	n=4 (11.1%)
Clinical practice	n=21 (58.3%)
Other	n=1 (2.8%)

7.3.3 Section B. Clinical management: Phases of the nursing process

This section includes the recommended drafted guidelines related to clinical management which includes the phases of the nursing process:

7.3.3.1 Question 5: Phase 1 of the Nursing Process: Subjective data

This guideline was recommended in round one and rephrased as suggested by the participants in round one see paragraph 7.2.2.1.: The knowledge about the phases of the nursing process can be assessed by doing a pre-test before the in-service training is conducted and a post-test at the end of the in-service training. One participant disagreed, and the remainder agreed. n=35 (97.2 %).

The nurse should collect the patient's subjective data (demographic, personal and social data) during the assessment, as shown in table 7.24. Data collected by the administrative clerk should be verified by the nursing staff. Two participants commented that it is not relevant to ask the number of dependants a patient has, but n=34(94.4%) agreed to this recommendation.

All participants n=36 (100%) agreed to the drafted guidelines about social habits.

All participants n=36 (100%) agreed that a comprehensive medical and family history should be taken of all patients as it is stated in the scope of practice for nurses (drafted regulation R786 of 2013) and introduced through the Nursing Act, 2005 (Act No. 33 of 2005).

Table 7.24: Phase 1 of the Nursing Process: Subjective information

Recommended drafted guidelines	Agree
5.1. The knowledge about the phases of the nursing process can be assessed by doing a pre-test before the in-service training is conducted and a post-test at the end of the in-service training	N=35 (97.2%)
5.2. The nurse should verify whether the administration staff of the HE collected the patient's subjective data (demographic, personal and social data) during the assessment, namely:	
5.2.1.Age of the patient	N=34 (100%)
5.2.2.Gender	N=35 (97.2%)
5.2.3.Marital status	N=35 (97.2%)
5.2.4. Dependants	N=34 (100%)

7.3.3.2 Question 6: Phase 1 of the Nursing Process: Objective data

The nurse should collect the patient's objective data during assessment which include vital signs and other special tests depending on the patient's condition and where applicable. The number of participants who responded varies from N=34 to N=36.

One participant disagreed on foot pulse monitoring, monitoring sensation and motor functions of the upper or lower limbs depending on the level of spinal surgery and intake and output and n=35(97.2%) agreed. Another participant disagreed on height monitoring, and n=35 (97.2%) agreed.

7.3.3.3 Question 6A: The nurse should be able to conduct a physical assessment of the patient, which include:

This applies to the professional nurse who is performing heart and lung auscultation. One participant disagreed, and n=35 (97.2%) agreed. Participants who disagreed indicated that "where applicable" should be added as it is not generally expected of every patient (Table 7.25).

Table 7.25: Objective data

Recommended drafted guidelines	Agree
6. The nurse should collect the patient 's objective data during assessment which include vital signs and other special tests below depending on the patient's condition and where applicable	
6. (A). The nurse should be able to conduct a physical assessment of the patient, which include:	
1. Foot pulse monitoring (When indicated)	N=35 (97.2%)
2. Continuous ECG monitoring (in high-risk patients)	N=36 (100%)
3. Monitoring sensation and motor functions of the upper or lower limbs depending on the level of spinal surgery.	N=35 (97.2%)
4. Circulation checks post plaster of Paris insertion	N=35 (97.2%)
5. Intake and output monitoring of fluids and meals	N=34 (97.1%)
6 (B) Special tests should be done and these form part of the assessment	
1. Haemoglobin	N=36 (100%)
6 (C). The nurse should be able to conduct a physical assessment of the patient, which include:	N=36 (100%)
1. The professional nurse performing heart and lung auscultation	N=35 (97.2%).

7.3.3.4 Question 7. Phase 5 of the Nursing Process: Evaluation

If the patient's condition does not improve the nursing care plans are re-evaluated and re-planned: A participant commented that continuous evaluation is important. All participants agreed. n=36 (100%).

7.3.3.5 Question 8. Documentation of Patient Records

Documentation should be done at all stages of the nursing process to ensure continuity of care. Participants agreed n= 35(97.2%) that the signature and designation of the person that was documenting should be clear.

Discharge reports should indicate patient education given. One disagreed n=35(97.2%) (Table 7.26).

Table 7.26: Documentation of Patient Records

Recommended drafted guidelines	Agree
1. Documentation should be done at all stages of the nursing process to ensure continuity of care	N=35 (97.2%)
2. Discharge reports should indicate patient education given.	N=35 (97.2)
3. Signature and designation of the person that was documenting should be clear	N=35 (97.2 %)

7.3.4 Section C: Human behaviour

7.3.4.1 Question 9. Health care professionals' behavioural problems

All participants agreed that a good relationship between the Nursing education institutions and hospital should be established. Establish a strengthened relationship with relevant stakeholders; one disagreed and N=35(97.2%) agreed as shown in table 7.27.

Table 7.27: Human Behavioural Problems

Recommended drafted guidelines	Agree
Health care professionals' behavioural problems may be addressed by nursing management as follows:	
1. Encouragement of positive behaviour amongst Health Establishment (HE) managers may contribute to quality care being delivered, reduce absenteeism which is a contributory factor to mismanagement of patients	N=35 (97.2%)
2 Establish a strengthened relationship with relevant stakeholders.	N=35 (97.2%)
3 Establish a good relationship between nursing education institutions and hospitals.	N=35 (100%)

7.3.5 Section D: Organisational factors

7.3.5.1 Question 10. Nursing leadership and management

All participants agreed. n=36(100%) to the recommended drafted guidelines as listed in table 7.28. A participant believed that mentoring is important for novice employees to ensure quality care.

Table 7.28: Nursing Leadership and Management

Recommended drafted guidelines		Agree
Mentoring and coaching		
1.	Introduction of mentors to coach and support the newly employed nurses and student nurses.	N=35 (100%)
2.	Ensure the induction and orientation of newly appointed staff members within the first eight (8) weeks after the appointment date.	N=35 (100%)

7.3.5.2 Question 11: Continuous nursing professional development

The participants n=36 (100%) agreed with these guidelines, although two participants voiced out their concerns about the poor attendance of the developed in-service training programme which might not be that much successful due to staff shortage. One participant disagreed that the refresher course should be done at six months' intervals n=35(97.2%).

Table 7.29: Continuous nursing professional development

Recommended drafted guidelines		Agree
1.	Ensure identification of knowledge gaps in each HE by conducting skills audits.	N=36 (100%).
2.	Ensure the development and implementation of a Professional Development Programme.	N=36 (100%).
3.	Refresher course at least six monthly in the Health Establishment on the following:	
1.	Anatomy and physiology	N=35 (97.2%)
2.	Pathophysiology of the most common diseases	N= 35 (97.2 %)
3.	Medication indication, contraindications, side effect, effects, action, rout and dosage	N=35 (97.2%)
4.	Control of drugs	N=35 (97.2%)

7.3.5.3 Question 12: Nursing monitoring and evaluation: Clinical audits

One participant disagreed on this recommendation and n=35 (97.2%) agreed.

Table 7.30: Clinical audits

Recommended drafted guidelines	Agree
. **Conduct clinical audits and check if the following are done as per guidelines, policies and regulations:**	
1. Patients 'reports if these are complete.	N=35 (97.2%)
2. Management and treatment techniques	N=35 (97.2%)

7.4 SUMMARY

Delphi method was applied to validate guidelines in two rounds. In these two rounds, the participants commented by adding their opinions, sometimes seeking clarity and additional information was added to the recommended drafted guidelines.

The validation process was terminated after round two. In spite of the changes to the guidelines some participants persisted with their opinions about a few validated draft guidelines.

The final consensus rate is as follows:

- The number of validated guidelines: 144
- Consensus reached at 100%: n=127 (88.2%)
- Consensus reached at 96-97% = n=17(11.8%

CHAPTER 8: DISCUSSION OF RESULTS, CONCLUSIONS AND RECOMMENDATIONS

8.1 INTRODUCTION

8.1.1 Brief overview of the study

This chapter provides a discussion of the results of this study that were used to develop validated guidelines that aim to contribute to the prevention of malpractice litigation in nursing practice in South African public and private sectors. Through the increased knowledge gained about South African nursing practice relating to patient safety and possible litigation in situations of malpractice.

It answers the following study questions:

1. What are the contributing factors that lead to adverse events in nursing care?
2. What are the validated guidelines that can be developed that contribute to the prevention of malpractice litigation in nursing practice?

The study was conducted in phases, each of which is discussed sequentially, followed by the conclusion and recommendations of the study.

8.1.2 Phase 1

8.1.2.1 Objective

To conduct a retrospective audit of adverse events resulting in malpractice litigation described in trial bundles from cases in the public healthcare sector in the Gauteng and Eastern Cape provinces.

To meet this objective, the researcher audited 98 trial bundles in Gauteng and 105 trial bundles in the Eastern Cape Provinces, with a total N=203.

The primary hypothesis was set for this study, that there is a difference in proportion of litigation cases due to (caused by) enrolled nurses (ENs) and or enrolled nursing assistants (ENAs) versus higher cadres of nurses, between the public and private cases, we assumed the prevalence of cases due to EN/ENAs was higher in the private cases than the public cases, as informed by the pilot results (refer to paragraph 4.3.4). However, the study has further shown through the large number of tests that there were many differences between the public and private healthcare sectors as illustrated in the following examples:

A Pearson Chi square test was applied, and statistical differences were identified between private and public healthcare sectors with specific reference to the following:

- not responding to clinical manifestations (p=0.001) and
- accumulation of errors (p=0.003).

In the public healthcare sector, adverse events were more likely to occur due to not responding to clinical manifestations. No statistical differences were identified between private and public healthcare sectors with reference to failing to apply guidelines (0.84) and accumulation of omissions (0.38) (refer to paragraph 6.8.3).

8.1.2.2 Hypotheses

The following hypotheses were set and answered for phase 1:

H0: There are no statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces **were rejected.**

H1: There are statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice which occurred in public hospitals in Gauteng and the Eastern Cape provinces **were accepted.**

8.1.2.3 The adverse events and the contributing factors identified during phase 1 of the study occurring in public hospitals in Gauteng and the Eastern Cape provinces

8.1.2.3.1 Clinical management

The clinical management referred to the nursing process, which consists of five phases, namely assessment, diagnosis, planning, implementation and evaluation. These further included observations, tests, interpretation and documentation. Clinical management contributed to 87.7% of adverse events in this study.

Assessment of patients is critical as it leads to the formulation of nursing diagnoses and further management of patients. The nurse has a responsibility to collect both subjective and objective data of the patient, interpret this data, formulate the nursing diagnosis and care plans. This study results have shown that patient safety was compromised. In a qualitative study, conducted in Sweden the participants indicated that the nurses should ensure that planning and implementation of care plans are coordinated to ensure good patient outcomes (Larsson & Sahlsten, 2016:1-8).

Formulating the care plans requires evaluation of the patients' condition to evaluate if the set goals were achieved (Refer paragraph 3.6). However, as shown in table 5.16, paragraph

5.3.3.6.1 a statistically significant difference (p=0.004) was identified between Gauteng and Eastern Cape provinces with reference to the incompleteness of the initial assessment. The Eastern Cape Province public healthcare sector was more likely to have incomplete initial assessments**.** The nurses have a responsibility to ensure that patients' needs are identified and planning is in place to attend to the patient's needs.

Poor assessment leads to misdiagnosis and adverse which compromise patient care. Proper patient assessment, planning and implementation of care plans implementation of nursing care plans leads to improved quality of care, minimises hospital stay, increases patient satisfaction. The National Core standard domain two "Patient Safety, Clinical Governance and Clinical Care" covers patient safety standards which guides the HEs specifically with clinical care and ethical practice including the prevention of the adverse events in the HEs (National Department of Health, 2011:6). However, the study showed that of the trial bundles that were audited, 1.5% patients were not assessed and 72.9% incompletely assessed. Miskir and Emishaw (2018:1-9) identified in their study that 50% of participants who responded indicated that the assessment of patients be conducted within the first 24 hours of patient admission. This is critical to enable the nurse to diagnose and plan the patient's care, preventing a delay in the management of the patient.

The study further revealed that special care plans were incomplete (68.5%), and 6.4% had no special care plans. Vital signs were not monitored as required. The results showed that the following vital signs were incompletely monitored: blood pressure (79.3%), pulse rate (78.8%), and foetal heart (70.4%). Also, failing to apply guidelines (91.6%) and not responding to clinical manifestations (79.4%). It is critically important to monitor patients, in order to identify any abnormalities which, warrant urgent attention. Vital signs are the fundamental aspects of the assessment of patients upon which the required management of patients are based. According to Cardona-Morrell, Prgomet, Lake, Nicholson, Harrison, Long, Westbrook, Braithwaite and Hillman (2016:9-18) serious adverse events may be avoided by recognizing early warning clinical signs and physiological deterioration in a patient's condition. They emphasise the monitoring of patients' vital signs to support an early warning system.

According to Jevon (2010:12), nurses should be able to respond and interpret vital signs which lead to preventable complications. The Scope of Practice of Nurses, Regulation 2598 as promulgated by the Nursing Act 50 of 1978 emphasises amongst others that patients are monitored, including their vital signs, assessment of patients' needs or problems, diagnosing, formulating care plans, implementation and evaluation of patients.

The study showed that multiple factors were identified in one litigated case. Similarly, Treacy and Stayt (2019:1) in their study identified that a multiple of factors influenced the identification and the response to patients deteriorating, due to a lack of knowledge of nurses. Consequently, patients received “sub-optimal care”.

In Case no. 8700/2013 13/3/2019, presented in the High Court of South Africa, Kwazulu-Natal Division Pietermaritzburg it was shown that a patient that was in labour, the foetal heart monitoring was not done according to the Maternity Care Guidelines of South Africa (2015). No care plans were formulated, nor was action taken when foetal distress was identified, resulting in the baby developing cerebral palsy.

The results have shown that in midwifery practice and Obstetrical Care had the majority of litigation cases in the public healthcare sector. In the public healthcare sector 70.4% of patients were admitted to the labour ward (Refer to paragraph 5.3.5.1), of which 94.4% developed cerebral palsy (Refer paragraph to 5.3.5.2.1.1). The midwife manages two lives, of which the life of the unborn child depends on meticulous management especially during labour. A significant difference (p=0.01) was identified between the Eastern Cape and Gauteng public healthcare sectors with reference to patients who had an adverse event in the labour ward. Gauteng public healthcare sector was more likely to have patients developing an adverse event in the labour ward (Refer to paragraph 5.3.5.1). According to Dr Chris Archer the state pays one third of the health budget to litigation “It's a very serious situation. And we are trying to find the solution to reduce the risk of damage to the child (Radio 702, 25 November 2016). The public sector does not have any form of liability insurance, consequently budgets meant for safe quality patient care is paid to litigation which may compromise patient care. Despite budget constraints the nurses should be provided with supporting measures which will enable them to provide safe quality patient care. Substantiated by Griggs (2012:27) in her study identified that the introduction of a safety perinatal nurse into the labour ward decreased Caesarean sections, admissions to neonatal intensive care and operative deliveries (forceps/vacuum) decreased.

8.1.2.3.2 Behavioural problems

The study identified that human behaviour (12.3%) contributed to adverse events (Refer to paragraph 5.3.61). Factors which were identified due to human behaviour included clinical manifestations not responded to (79.4%), an accumulation of errors (41.8 %), not following guidelines (91.6%), administering incorrect treatment (16.0 %) and accumulation of omissions (49.8 %) (Refer to table 5.50). Multiple factors due to human behaviour contributed to malpractice litigation within one litigated case. It is critical that the nursing staff in the HEs is constantly reminded about the Code of Ethics is a binding document which entails content that the nurses must comply to with their practice and ethical decision making (South African Nursing Council,

2013). Furthermore, factors such as lack of accountability amongst the nurses, a culture of mediocrity rather than excellence, demotivated staff, and even an erosion of professional ethics, are all to blame (National Department of Health, 2011:1). Fischer, Lange, Klose, Greiner and Kraemer (2016:36) identified that personal factors such as lack of knowledge and negative attitude towards the implementation of guidelines were barriers to the implementation of guidelines in the HEs. Child (2014:1) found that of 86 births at a particular hospital in South Africa 68 had cerebral palsy. According to Adotevi (2011:1), a 27-year-old mother died during child-birth whilst delivering her second baby. The mother was left unattended whilst in labour, which resulted in the baby being delivered on the hospital floor. During post-delivery, the mother was further neglected by the nursing staff, and this resulted in the death of the 27-year-old. Reason (2000:768) explains that forgetfulness and negligence, and not following specific instructions lead to unsafe acts. Nassar, Abdou and Mohmoud (2011, 243-250) are of the opinion that there is a relationship between management styles and nurses' retention at private hospitals. Explained further, management styles in the HEs play a vital role in promoting workplace empowerment, organizational commitment and job satisfaction amongst nurses. The required management styles include personal traits and behavioural characteristics of the person in a position to influence group interaction and achievement of organizational goals. In their study Nassar, Abdou and Mohmoud (2011, 243-250) identified authoritative management style was indicated by 37.5% participants that results in staff turnover. These study results confirm that behavioural problems occur in the HEs is as a result of organisational factors.

8.1.2.3.3 Organisational and administrative factors

It was identified in this study as shown in paragraph 5.3.6.1 that organisational (13.8%) and administrative factors (4.9%) contributed to malpractice litigation. Organisational and administrative factors that contributed to adverse events included system failures (12.3%) (Table 5.50). Adverse events resulted from the lack of beds, faulty monitoring equipment specifically the cardiotocograph machines, transport and too few doctors to perform Caesarean sections are described briefly in paragraph 5.4.5.1.1.

The OHSC conducted annual inspections of the HEs to ensure that there was compliance to the National Core standards. During 2014/ 2015, 2015/2016 and 2016/2017 financial years the Gauteng province scored 75%, 61% and 60% respectively and the ECP scored 46%, 48% and 45% on the availability of medicine and supplies (OHSC:2017).

Coli, Anjos and Pereira (2010:324-30) are of the opinion that the occurrence of adverse events relates to management system failure, rather than negligence and incompetence of the staff. Many of the adverse events that occur are as a result of environmental and organisational factors (Runciman et al., 2006:23). These factors include workload management, staff shortages,

damaged or faulty equipment, transportation, poor organisation of teams and staff, and inadequate policies and guidelines (Runciman et al., 2006:28-48). In a study conducted in Florida, a participant voiced a dissatisfaction about managers who emphasise the importance of adhering to standards but the broken machines such as dynamaps were not fixed thus making it difficult to monitor patient's vital signs. The study further revealed that one participant recalled that a unit supervisor refused to assist her to initiate an intravenous line as she claimed to be too busy although she was busy on the telephone and computer in her office (Dyess et al., 2016:309-310). Tang, Shei, Yu, Weil and Chen (2007:447-457) also confirmed in their study that a heavy nursing workload, poor application of policies and procedures, new staff who may be unaware of the policies, lack of equipment, and system failures were identified as contributing factors to an increased risk for medical-legal errors. Manyisa and Van Aswegen (2017:28) explained that workload, HIV/AIDS epidemic, shift work, long working hours, poor infrastructure, inadequate resources and shortage of staff were found to be the main factors that attributed to poor working conditions in public HEs.

Baraki, Girmay, Kidanu, Gerensea, Gezehgne and Teklay (2018:1-9) identified that the nurses who worked in the HEs where there was an adequate supply of material resources were more likely to implement the nursing process while those who worked in stressful environments were less likely to implement the nursing process (Baraki et al.,2018:1-9).

8.1.2.4 Adverse events

8.1.2.4.1 Severity of the adverse events

During the audit analysis, the adverse events were categorised according to the Safety Assessment Code (SAC) (SA Health Risk Management Framework, nd). Also the study revealed that the majority of the adverse event were extreme (70.2 %). A study that was conducted to identify factors related to the retained surgical instruments revealed that 54% of cases were missed on initial postoperative assessment. The study further revealed that 56.5% surgical counts reported as being correct and 31% cases were reported due to incorrect swab count during surgical intervention (Styskel, Wernick, Mubang, Falowski, Papadimos and Stawicki, 2016: 5).

Haukland, Mevik, von Plessen, Nieder and Vonen (2019:1-8) identified in their study that in 0.3% of hospital admissions, adverse events contribute to inpatient death. Furthermore, the study identified that patients dying in hospital experience seven times the rate of severe adverse events (38.4%), inpatient deaths (27.9%), lower respiratory infections (2.81%), medication harm (8.94%)

and pressure ulcers (4.85%). The above mentioned studies support this study results as the extreme adverse events were also identified in other countries. Applying the Pearson Chi-Square statistical test, a significant difference (p=0.01) was identified between the Eastern Cape and Gauteng healthcare sector with reference to the severity of adverse events which led to malpractice in nursing practice. Gauteng healthcare sector was more likely to have extreme adverse events, as explained in paragraph 5.3.6.2.

8.1.2.4.2 Healthcare professionals responsible for adverse events

This objective has shown that both nursing and medical staff (70.9%) contributed to adverse events (Refer to paragraph 5.3.5.4). The results further showed that the midwives (84.1%) were mostly involved in the occurrence of adverse events audited, as described in paragraph 5.3.5.5.

8.1.2.4.3 The outcome of the adverse events

The researcher may confirm that the care that was rendered in these HEs in Gauteng and ECP public healthcare sectors were the result of substandard care. As a result of the adverse events, 80.3% of the patients had their quality of life affected, 70.9% were disabled, 67.0 % had an increased hospital stay, 15.8% had additional surgery, and 2% died (Refer to paragraph 5.3.5.3). Applying the Pearson Chi-square statistical test, significant differences were identified between Eastern Cape and Gauteng healthcare sector with reference to the outcomes of the adverse events specifically disability (p=0.01), death (p=0.01), surgery (p=0.01) and quality of life affected (p=0.01). These results show that patients are more likely to have additional surgery in the ECP and to die as a result of an adverse event which occurred in the ECP, while patients are more likely to be disabled from adverse events which occurred in the Gauteng public healthcare sector. Makary and Daniel (2016:353) identified that the third leading cause of death in the United States of America is medical error. They examined death certificates and found from 2000-2002: 575 000 deaths occurred and in 2008 180 000 deaths due to medical error and not what was written on the death certificate.

Disability in a family is a burden to family, community and the state. Bazzano, Wolfe, Zylowska, Wang, Schuster, Barrett, Lehrer, Wolfe and Zylowska (2015: 298) found in their study that stress among parents and other primary caregivers of children with developmental disabilities are associated with a lower quality of life, unhealthy family functioning, and negative psychological consequences.

Babies born with cerebral palsy are costing the state millions of rand as shown in the case in Gauteng, in which a five-year child who suffered cerebral hypoxia at birth was paid out R19 million rand in 2018, due to the negligence of the midwife and doctor. The child suffered not only brain

damage, but will never be able to "…walk, talk or eat by herself, due to the negligence of some doctors and nurses at…" (Venter, 2018:1).

8.1.3 Phase 2

8.1.3.1 Objective

To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces.

A total of 122 trial bundles were audited in the private sector by two master's students. The data obtained from the private and public healthcare sectors were merged, and a comparative statistical analysis applying the SPSS was completed.

8.1.3.2 Outcome of Hypotheses

The outcome of the hypotheses set for this phase were as follows:

H0: There are no statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice between the public and private healthcare sectors **were rejected.**

H1: There are statistical differences between the analysis of adverse events which led to malpractice litigation in nursing practice between the public and private healthcare sectors **were accepted.**

8.1.3.3 The comparative analysis of adverse events and the contributing factors identified during phase 2 of the study occurring in private and public healthcare sectors

8.1.3.3.1 Clinical management

The audited trial bundles in the private and public healthcare sectors showed deficits in the care that were provided. Clinical management contributed to 89.5% of the adverse events in these healthcare sectors (refer to paragraph 6.8.1).

The clinical management included the nursing process, tests, documentation and interpretation of clinical manifestations. In a qualitative study that was conducted in Catalan the majority of participants reported that there was continuity of clinical management at all levels care in the HEs (Waibel, Vargas, Aller, Coderch, Farré & and Vázquez, 2016:466). In addition, the participants reported that there was continuity of adequate information sharing via computer (Waibel et al, 2016:466).

As described in paragraph 6.5.6.1, the study has shown that the initial assessments of patients were incomplete (53.8%) and (9.5%) were not done. A statistically significant difference (p=0.01) was identified between the public and private healthcare sectors regarding the initial assessments. The initial assessment of patients in the public healthcare sector was more likely to be incomplete. In addition, care plans (47.7%), special care plans (46.5%) were incomplete and implementation of care plans were not implemented (26.5%).

Results further show a statistically significant difference (p=0.01) in taking action based on the diagnostic test results. The public healthcare sector was more likely to act based on diagnostic test results as described in paragraph 6.5.6.11. The results show that the vital signs were not monitored as prescribed. The following observations were incompletely done blood pressure (52.9%), pulse (56.6%), foetal heart (44.6%) and respiration (54.8%). Statistical significant differences (p=0.01) were identified between the public and private health care sectors with

regards to the monitoring of patients. The public healthcare sector was more likely to monitor patients incompletely. This could be due to greater availability of resources in the private health care sector than the public healthcare sector. In a study that was conducted in a public hospital complex 93.7% indicated that there were inadequate resources to provide quality care in the maternity departments (Gcawu, 2012:54). Substantiated further Eygelaar and Stellenberg (2012:1-8) identified in their study that there are numerous barriers in public hospitals in the rural areas which influence the quality of patient care such as poor staffing and resources.

The sole responsibility of the registered nurse as indicated in the Nursing Act, 2005 (Act No.33 of 2005) which is fundamentally critical, is to assess, diagnose and plan care for patients. According to Regulation 767 Acts or Omissions as promulgated through the Nursing Act, 33 of 2005 a registered nurse could be disciplined should she/he fail to "…carry out such acts in respect of the assessment, diagnosis, treatment, care, prescription, collaboration, referral…" (Refer to paragraph 3.4.1.1.1).

Substantiated in a study conducted in three governmental hospitals in Ethiopia about the implementation of the nursing process, Semachew (2018:1) found that 31.7% of patients had no nursing diagnosis, 54.7% of nurses stated their plan of care was based on priority, while 51.2% did not document their interventions and 53.0% did not evaluate their interventions. This study substantiates that the implementation of the nursing process is important and that nurse leaders should supervise the implementation.

In the South African High Court, Free State Division (2014) CASE **NO: 2302/2014**, the plaintiff who as a result of spinal surgery developed a Cauda Equina Syndrome gave evidence about the nurses not responding to complaints of numbness in her lower limbs. It was further identified that the care plans in an intensive care unit were prescribed by an enrolled nurse who failed to prescribe the monitoring, specifically of the patient who had spinal surgery. This plan was not checked and co-signed by the registered nurse. Poor monitoring and not reporting to the surgeon, resulted in the loss of sensation and motor action of the patient's limbs. The plaintiff consequently developed paraplegia, incontinence of urine and faeces.

Van Waart, Ranchod, Taylor and Taylor (2018:149) explained that the healthcare in South Africa is in a state of paralysis, due to poor service delivery, especially in maternity care.
According to the researcher this is not acceptable; poor documentation and poor monitoring of patients are not an excuse; it is a violation of safe quality care and equates to patient neglect.

The results show that there is no statistical difference (p=0.27) between private and public healthcare sectors concerning the clinical management of patients. This indicate that

substandard care is provided in private and public healthcare sectors in the Eastern Cape province, Gauteng and Western Cape Provinces.

8.1.3.3.2 Behavioural management

Challenges such as failure to respond and attend to patients' needs are linked to behavioural problems. This is confirmed by the results of this study which revealed that human behaviour (26.5%), failing to give treatment as required (49.8%), accumulation of errors (41.8 %), behaviour, (26.5 %), and accumulation of omissions (49.8 %) contributed to adverse events (refer to paragraph 6.8.3). A study that was conducted in selected private hospitals in the Western Cape Metropolitan area revealed that 32% of respondents agreed that they are not always honest with patients and 78% agreed that they function in an area where there is trust and common purpose (Stellenberg & Dorse (2014:1). This study results have found that in the private sector failure to give treatment as required, incorrect treatment, and accumulation of errors were likely to occur as described in paragraph 6.8.3. Härkänen, Kervinen, Vehviläinen-Julkunen, Ahonen and Turunen (2015:297) found in their study that patient harm was caused by 63.4% medication administration errors, 18.3% documentation errors, 59.1% incorrect administration technique, and 3.4% of errors. Human behavioural problems include physical abuse and patient neglect. A study conducted by Meghan, Joshua, Vogel, Özge, Fawole, Titiloye, Olanrewaju, Olutayo, Oyenira, Ogunlade, Metiboba, Osunsan, Idris, Alu, Olufemi, Gülmezoglu and Hindin (2016: 640) identified that patient abuse was common during labour; the researchers reported that patients are being slapped, shouted at, intimidated, and sometimes neglected. Nurses' job satisfaction is the outcome of good behaviour management and may result in quality patient care. The results of a study that was conducted in Pakistan by Farman, Kousar, Hussain, Waqas, and Gillani (2017:511-519) revealed that 68.5% of participants believed the quality of care that was provided in the HEs was positively related to nurses' job satisfaction nurses work load, stress and unsafe work environment.

8.1.3.3.3 Organisational and administrative factors

Organisational (23.7%) and administrative (6.5%) principal types contributed to the malpractice litigation in this study (Refer to paragraph 6.8.1). The private healthcare sector was more likely to have adverse events that occurred due to organisational and administrative problems.

The study further showed that system failure (21.5 %), lack of supervision (17.5 %), lack of training (19.4 %) and lack of knowledge (28.9 %) led to malpractice litigation (Refer to paragraph 6.8.3).

In the public healthcare sector, South Africa, the challenges include a gross shortage of doctors and nurses. To curb this shortage, community health workers are used to address the shortage. Unfortunately, there is no standardised job description for these community health workers (Young, 2016:3). Van Waart et al. (2018:149) explain further that factors, such as poor resources and poor management in the public sector lead to malpractice litigations. In addition, Stellenberg, Van Zyl and Eygelaar (2015:1-7) identified in their research that the knowledge of healthcare workers of the integrated management of childhood illness was inadequate to provide safe, quality care. Khamisa, Oldenburg, Peltzer and Ilic (2015:653) identified in their study that poor management of resources, burnout, job dissatisfaction and workload negatively affected nursing staff performance and patient care.

The private healthcare sector is fragmented, there is a lack of accountability, and high expectations which lead to increased malpractice litigation (van Waart et al., 2018:149). The Market Enquiry Commission (2016:7) identified that a weakness existed in accountability among medical practitioners. They do not subject themselves to peer review or deliver on the outcome of patient care and this is also applicable to academics who deliver a service in private practice. Academics have shown minimal leadership in evidence-based practice in private health.

There is a disparity between the patients that receive healthcare services in South Africa. The study further revealed that the majority of the patients in this study were not employed (56.9%) and the public healthcare sector was more likely to have patients that were not employed, as shown in table 6.10. The public healthcare sector is funded by the government and in the private healthcare sector patients fund themselves, and the services are rendered at a high cost (Young, 2016: 3). The private healthcare sector consumes 60% of the health expenditure and is responsible for less than 20% of the South African population facilities (Pillay, 2009:2). In contrast, the public sector is under sourced and overused, and is being characterised as being ineffective in meeting the criteria for affordable and accessible healthcare. Safe quality care should be ensured, whether in private or public healthcare sector. Fortunately, South Africa is moving towards universal healthcare coverage. The National Health Insurance (NHI) Bill was presented in the South African Parliament and will soon be promulgated, providing access and quality healthcare to all (NHI Bill, 2019).

8.1.3.4 Adverse events

8.1.3.4.1 The severity of the adverse events

Results have shown that the majority of the adverse events were extreme 70.2%, 17.2% of the adverse events were major, and 10.2 % were moderate. Extreme adverse events are more likely

to occur in the public healthcare sector; major, moderate and minor are more likely to occur in the private sector (refer to paragraph 6.8.2).

8.1.3.4.2 Health professionals responsible for the adverse events

In this study, the midwife was mostly involved in adverse events (43.4%), followed by professional nurses (33.9%), enrolled nurses (13.5%) and enrolled nursing assistants (9.3%) (Refer to paragraph 6.7.6). The public healthcare sector was more likely to have midwives involved in the occurrence of adverse events. In the private healthcare sector, the professional nurse, together with the enrolled and enrolled assistant nurses, were more likely to be involved in adverse events. The SANC as the regulating body has a responsibility to regulate the nurse's scope of practice, both in public and private sectors, (draft regulation R786 of 2013) as promulgated through the Nursing Act 33 of 2005. At times this regulation is ignored, and a nurse performs a task that is not within her/his scope of practice which leads to malpractice litigation.

In the Bloemfontein High Court CASE NO: 2302/2014, the plaintiff who had spinal surgery, her care was entrusted to the enrolled nurses resulting in suboptimal care provided. This patient was admitted to the Intensive Care Unit, and the registered nurse failed to supervise the enrolled nurse. Furthermore, a study conducted in the Netherlands about the study scope of practice of registered nurses identified that qualifications and task allocation were not considered during delegation of duties and this led to adverse events occurring (Wagner, Merten, Zwaan, Lubberding, Timmermans & Smits, 2016:3).

8.1.3.2.5 The outcome of the adverse events

The study has shown in paragraph 6.7.3 that the quality of life of most patients were affected (76.0%) - 71.4% required an increased hospital stay, 53.8% were disabled, 26.2% required additional surgery and 8.9% died. These results in this study revealed that patients were more likely to die in the private healthcare sector and have additional surgery. In public healthcare sector patients were more likely to develop a disability as a result of an adverse event and more likely for patients to have their quality of life affected. Cognisance should be taken that in South Africa today, the Social protection expenditure will rise from R162.6 billion in 2018/19 to R202.9 billion in 2021/22, at an average annual growth rate of 7.6 per cent. This includes the social protection expenditure on disability. The outcome of malpractice litigation costs South Africa billions of rand (South Africa Budget Review, 2019:62). The National Minister Dr Aaron Motsoaledi reported malpractice litigation of R90 billion rand pending in March 2019 (SAPA 2019).

Young (2016: 3) is of the opinion that the advantages of private healthcare include quality care; however, this study results contradict this opinion. The results have confirmed that irrespective

of the standards that are expected to give good outcome of care, substandard care is sometimes provided in both private and public healthcare.

In the public healthcare sector, the government funds the healthcare services and billions of rand are allocated for patient safety, but substandard care still persists. South Africa is a developing country with the largest economy on the African continent with a population of 56.4 million and is part of the emerging world markets (Africa Health, 2018:1). In 2017 South Africa spent 9% of its GDP on healthcare service delivery which is 4% higher than the WHO's recommended spending for a country of its socioeconomic status. To ensure patient safety the consolidated government expenditure for 2018/2019 towards the public healthcare sector was R208.8 billion (South Africa 2, 2019:57). Shortage of staff is amongst the priorities that the government of South Africa intends to address by introducing the National Health Insurance.

This study has revealed that there are various factors as shown in table 6.57 that contribute to malpractice litigation in nursing practice in the public and private healthcare sectors. In the public sector the majority of adverse events were classified as severe.

8.1.4 Phase 3: Objectives 3 and 4

- To use the results of objectives 1 and 2 to develop a set of guidelines that will contribute to the prevention of nursing malpractice litigation in South Africa.
- To validate the developed guidelines using the Delphi method.

Based on the analysis of the outcome of objective 2, draft guidelines were developed and validated by applying the Delphi method.

8.1.4.1 Brief overview of the guideline development process

The purpose of this study was to develop and validate guidelines that will contribute to the prevention of adverse events that culminate in nursing malpractice litigation in South Africa:

To compare and contrast adverse events that led to malpractice litigation in the private healthcare sector in Gauteng and Western Cape provinces with those litigated in the public healthcare sector in Gauteng and Eastern Cape provinces.

Based on the analysis and merged data (325 cases) that were obtained from the private (122) and public healthcare sector (203), malpractice litigation trial bundles that were audited in phase 1 and phase 2 the guidelines were developed to achieve objective 3 of this study.

The WHO guideline development process was followed to develop guidelines, as described in chapter 4. Four members formed the guideline development group (GDG).

The following formed the GDG:

- The principal investigator is an expert witness in malpractice litigation with her focus area in quality and safe patient care
- Co-supervisor in the PhD study is an expert in quality assurance,
- A biostatistician is a co-investigator of the main study
- PhD student, a sub-investigator of the main study and chairperson of the GDG.

The researcher was guided by the results of the study, literature research, the theoretical frame work, SAC and nursing process that guided the study to develop the guidelines, which are shown in table 8.1.

Table 8.1: Summary of the development of guidelines

Study results	Drafted guidelines	Literature
Clinical management n=291(89.5%)	Section B. Clinical management: Phases of the nursing process	3.7 Clinical management3.6 nursing process
Human behaviour n=98(30.2%)	Section C: Human behaviour	3.8 Human behaviour problems
Organisational n=77(23.7%) Administrative n=21(6.5%)	Section D: Organisational factors	3.4 legislation 3.5 patients' rights 3.9 organisational factors 3.9.2 leadership

8.1.4.2 Validation process applying a Delphi method: A quantitative approach

The Delphi method was applied in two rounds to reach a consensus from the experts that were selected to participate in the process. Experts were invited online, as described in chapter 4, paragraph 4.5.4.2. The return rate of N= 82 questionnaires which were sent to experts was N=60 (73.1%) in round one. Participants included the experts who were members of the South African Nursing Council, Council for Health Service Accreditation in Southern Africa (COHSASA), Heads of Nursing schools at universities and nursing colleges, Provincial Department of Health, specialists in clinical care and academia. Three participants were from Qatar, Germany and Tanzania, one from each country. The results are presented in chapter 7. The criteria set for the consensus Delphi method was set at 80%. Only two guidelines were deleted as the agreement score was below 80% and the participants had a lot of negative comments regarding these draft guidelines (refer to paragraph 7.1).

8.1.4.2.1 The outcomes of the validation process

A total of 144 validated guidelines are recommended, as described in annexure 9. The guidelines are grouped according to the principal incident types that were associated with adverse events. Administrative and organisational principal types were incorporated as one principal type.

Each guideline has sub guidelines:

- Clinical Management
- Human Behaviour
- Organisational.

8.1.4.2.1.1 Clinical management

This principal type has **63 validated guidelines** that are recommended to ensure that the nursing process phases are followed which include interpretation, responding to clinical manifestations and tests when patients are receiving nursing care in the HEs.

8.1.4.2.1.2 Human behaviour

In this principal type, the researcher recommends that healthcare professionals' behavioural problems should be addressed by nursing management. Staff motivation, support, coaching and mentoring are recommended in the HEs. **Fourteen validated guidelines** are being recommended to address human behavioural problems.

8.1.4.2.1.3 Organisational factors

In this section, the validated guidelines are subdivided into:

(i) Nursing leadership, administration and management

It is recommended that the HE managers should ensure that there are effective leadership, active collaboration and good governance, effective planning and resource management are in place. **Twenty validated guidelines are recommended.**

(ii) Mentoring and coaching

Supervision, support, orientation and induction of staff are recommended in this principal type. Four validated guidelines are recommended.

(iii) Operational management

In this guideline, it is recommended that the HE should ensure that operational plans are implemented in the wards/units and this can be done by ensuring the there is effective implementation of institutional plans and unit operational plans. Thirteen validated guidelines are recommended.

(iv) Continuous professional development (CPD)

It is recommended that the HE managers ensure that staff is developed and that the staff development programme is in place. Nineteen validated guidelines are recommended.

(v) Nursing monitoring and evaluation

It is recommended that the HEs should ensure that a clinical audit is conducted which will include clinical management, organisational and human behavioural management according to the validated guidelines. Eleven validated guidelines are recommended.

8.2 CONCLUSION

Based on the International classification for patient safety (WHO, 2009:1-154) and the Generic Reference Model (GRM), Runciman et al., (2006: 6) identified the contributing factors that led to the adverse events identified in the study that resulted in litigation. These formed the basis of the guidelines that will contribute to the prevention of nursing malpractice litigation in South Africa.

Contributing factors identified, resulting in litigated adverse events included:

8.2.1 Clinical management

Clinical management contributed to 89.5% of the adverse events leading to malpractice litigation in nursing practice and included the nursing process, tests, documentation and interpretation of clinical manifestations and tests.

Paragraphs 6.5.6.1 and 8.2.2.3.1 show that the initial assessment of patients was more likely to be incomplete, as were care plans in the public sector. However, the public sector was more likely to take action on diagnostic tests (Refer to 6.5.6.11; 8.2.2.3.1).

In contrast, the public healthcare sector was more likely to incompletely monitor patients, the results showing that the vital signs, such as blood pressure, pulse, foetal heart and respiration, were not monitored as prescribed. This study and other studies as indicated in this chapter confirm that there are factors that contribute to malpractice litigation nationally and internationally and factors include behavioural factors which is sometimes due to organisational factors that lead to poor clinical management.

8.2.2 Behavioural management

These included nursing failures to respond and attend to patients' needs. The study results revealed that human behaviour (30.2%), failing to give treatment as required (49.8%), accumulation of errors (41.8%), behavioural (26.5%) and accumulation of omissions (49.8 %) contributed to adverse events leading to malpractice litigation in nursing practice (Refer to paragraph 6.8.3). Behavioural factors such as lack of support to the newly qualified nurses may lead to the occurrence of behavioural problems in the HEs. The participants in a study that was conducted highlighted that when a newly qualified nurse is on duty the staff experience many problems due to inefficiency in practical work, which is due to the shortcomings of internships (Ashghaly, Oskouie & Ghaffari, 2016:335).

The study further revealed that the nurses in the private sector were more likely to fail to give treatment as required or give incorrect treatment, as well as the accumulation of errors.

8.2.3 Organisational and administrative factors

Organisational (23.7%) and administrative (6.5%) principal types contributed to the malpractice litigation in this study (Refer to paragraph 6.8.1). The private healthcare sector was more likely to have adverse events leading to malpractice litigation in nursing practice that occurred due to organisational and administrative problems.

The study further showed that system failure (21.5 %), lack of supervision (17.5 %), lack of training (19.4 %) and lack of knowledge (28.9 %) led to malpractice litigation (Refer to paragraph 6.8.3).

In the public healthcare sector of South Africa, the challenges include a gross shortage of doctors and nurses. To curb this shortage, community health workers are used to address the shortage. Unfortunately, there is no standardised job description for these community health workers (Young, 2016:3; Van Waart et al., 2018:149).

Quality patient care is to be provided irrespective of the challenges that are encountered in the HE.

The principal type overlapping was identified as human behaviour which may lead to poor clinical management as well as poor management which may lead to poor clinical management. Thus the validated guidelines as recommended to address behavioural factors should be applied to ultimately provide safe quality care to prevent the ripple effect behaviour has in the clinical environment on patient care.

8.2.4 Adverse events and their outcome

Using the Safety Assessment Code (SAC) Matrix (SA Health Risk Management Framework, nd), the study revealed that the majority of the adverse events leading to malpractice litigation in nursing practice were extreme (70.2 %) (Refer to paragraph 6.8.2). Gauteng healthcare sector was more likely to have extreme adverse events, as explained in paragraph 5.3.6.2.

Patients are more likely to have additional surgery in the ECP and to die as a result of an adverse event which occurred in the ECP, while patients are more likely to be disabled from adverse events leading to malpractice litigation in nursing practice which occurred in the Gauteng public healthcare sector.

While extreme adverse events leading to malpractice litigation in nursing practice are more likely to occur in the public healthcare sector, major, moderate and minor events are more likely to occur in the private sector (Refer to paragraph 6.8.2).

These results also reveal that patients are more likely to die in private healthcare or have additional surgery.

In public healthcare, patients are more likely to develop a disability as a result of an adverse event and it is more likely for patients to have their quality of life affected.

The outcome of malpractice litigation costs South Africa billions of rand (South Africa, 2019:62).

8.2.5 Healthcare professionals responsible for adverse events

The study results revealed that both nursing and medical staff (70.9%) contributed to adverse events leading to malpractice litigation in nursing practice (Refer paragraph 5.3.5.4).

Importantly, the results further showed that the midwives (84.1%) were mostly involved in the occurrence of adverse events leading to malpractice litigation in nursing practice, as described in paragraph 5.3.5.5.

The public healthcare sector is more likely to have midwives involved in the occurrence of adverse events. In the private healthcare sector, the professional nurse, together with the enrolled and enrolled assistant nurses, are more likely to be involved in adverse events. Aylward, Crowley and Stellenberg (2016:128) found in their study about the role of patient care workers in private hospitals in the Cape Metropole, South Africa that “Patient care workers are involved in direct patient care and spend much time with patients, often not working under direct supervision of registered nurses despite limited training and lack of regulation”. The researcher is of the opinion as identified in this study that adverse events leading to malpractice litigation in nursing practice are escalated with the use of substandard staff in nursing care practice.

8.3 STUDY STRENGTHS AND WEAKNESSES

8.3.1. Study strengths

This study has the following strength:

This is the first study of its kind conducted nationally and internationally in which trial bundles were audited of cases which were either completed in a court of law or settled out of court to identify factors which contributed to malpractice litigation in nursing practice.

This study was conducted in the three provinces of South Africa both in public (Gauteng and Eastern Cape provinces) and private health care sectors (Western Cape and Gauteng provinces) to identify the factors that contributed to the adverse events that led to malpractice litigation in nursing practice South Africa. The data was collected by the PhD student in the public healthcare

sector Gauteng and Eastern Cape provinces and the two master's degree students individually collected data in the private healthcare sector Gauteng and Western Cape provinces.

The guidelines that were developed were validated by experts from the nine (9) provinces of South Africa with expertise in clinical, academics in healthcare, consultation in health systems, accreditation of hospitals, policymaking in healthcare, regulating bodies in healthcare, writing healthcare standards for health establishments and clinical practice (refer to paragraph 4.5.4.)

The escalation of litigation may be curtailed through this study and may save the State billions of rand that are lost through medical-nursing malpractice litigation pay-outs.

This study can be used to create a platform for further research as described in paragraph 8.4.1.

The researcher prevented biasness by ensuring that the data that was collected was strictly done according to the audit instrument. In addition to avoid biasness the supervisor of the study, who is the principal investigator validated 35% of the data collection in Gauteng province by crosschecking the instrument where the data was captured and the trial bundles that were audited.

8.3.2. Study weaknesses

The study cannot be generalised internationally as it was conducted in the context of South Africa.

During data collection, the researcher observed that the filing system in some data collection settings was poor as in some offices files were found on the floor. The files were brought to the researcher or the researcher fetched the files from different Offices of the State Attorneys. All available files that met the inclusion criteria were retrieved, but it could be possible that not all files were obtained.

One hundred and twenty-two cases (61%) of the pre-determined sample size of 200 planned cases that involved adverse events leading to malpractice litigation in nursing practice which occurred in the private healthcare sector were audited. Obtaining trial bundles posed a challenge as these could only be obtained from lawyers who agreed to allow the master's students to access files at their offices.

The validated guidelines were not tested and could be a limitation of the study.

Biasness may have influenced the outcome of this study as there may have been factors that might have been under represented in this study.

8.4 RECOMMENDATIONS

8.4.1 Further research

i. The study has revealed that the majority of adverse events leading to malpractice litigation in nursing practice have occurred in midwifery / obstetric practice in the public healthcare sector.

ii. Thus, the researcher recommends that further research is to be conducted to identify the factors that contribute to the escalated malpractice litigation in midwifery practice which should include the training of midwives and their clinical practice.

iii. The researcher further recommends that research is undertaken in the private healthcare sector to explore nursing practice, specifically staff allocation and scope of practice of individual nurse categories.

iv. It is recommended that the study should be repeated in the other provinces.

v. It is further recommended that the guidelines should be tested in a pilot study before being implemented on a larger scale

8.4.2 Ensure that patients' rights are protected

It is the responsibility of each country to ensure that patients' rights are protected which include access to quality healthcare. This can be achieved by ensuring that safe quality patient measures are in place in the HEs. The theoretical framework that guided this study emphasises factors that contribute to safe quality patient care (WHO, 2009:1; Runciman et al., 2006:6).

8.4.3 Continuous professional development (CPD)

Regulations concerning CPD should be promulgated to ensure that nurses are competent, skilled and knowledgeable in their clinical practice.

8.4.4 Validated guidelines

The validated guidelines as described in annexure 9 should be implemented to contribute to the prevention of malpractice litigation in nursing practice.

8.5 SUMMARY

The researcher concludes that patient care is compromised due to negligence.

This study has shown that there are numerous factors in the HEs such as organisational, behavioural and clinical management that may lead to adverse events, resulting in malpractice litigation.

The purpose of this study was to develop validated guidelines that will contribute to the prevention of malpractice litigation in nursing practice in South Africa.

The theoretical framework that was applied in this study guided the researcher to identify and describe the contributing factors which led to an incident that consequently resulted in a negative outcome for the individual and organisation (WHO, 2009:154). The GRM which underlies the universal patient safety classification formulated by Runciman et al. (2006:6), and the International classification for safety (WHO, 2009:154) were selected to guide this study.

The philosophical underpinning of this study as guided by the critical realism theory as described in paragraph 2.3. has identified the depth of the problem in malpractice litigation in nursing practice. Consequently, it has uncovered that more research is required in this field to provide safe quality care to patients.

In South Africa today, the South African Constitution Act, 1996 (Act 106 of 1996) provides sections for the right to health care, namely:

- Access to healthcare services including emergency services and reproductive health
- Basic health care for children.

Subsequently, following the implementation of the Constitution, the South African National Health Act, 2003 (Act No 61 of 2003) was introduced. This Act states the right to the mental and physical well-being of every individual and that standards of care will be provided. Following the introduction of the Health Act, 2003 (Act No 61 of 2003) the National Health Amendment Act, 2013 (Act No 12 of 2013), the Office of Health Standards Compliance (OHSC) was established. In 2016 the OHSC introduced a complaint call centre for the public where complaints about healthcare could be lodged. In addition, the patient's charter is displayed in the HEs, the internet and social media have all become supportive measures for patients to become aware of their rights in healthcare. Thus, the patients' expectations for safe quality care in healthcare has increased; this may contribute to an increase in litigation.

Even though these measures are in place to ensure that quality patient care is rendered in the HEs, substandard care is still provided to patients. Substandard care may lead to adverse events, leading to malpractice litigation (Hwang, 2018:1). The Acting Chief Litigation Officer of the Department of Justice and Constitutional Development (DOJCD) has confirmed that the principal amounts paid out for litigation on behalf of the National Department of Health by the offices of the State Attorney amounted to a sum of R 498 964 916.72 during the 2013/2014 financial year. Furthermore, the Health Minister Dr Motsoaledi (March 2019) announced that South Africa faces litigation in public healthcare of R90 billion rand. This confirms that South Africa is in a crisis of escalating malpractice litigation that leads to a pay-out of billions of rand. This money could have been saved and used to purchase resources that will assist in providing quality care.

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ANNEXURES

ANNEXURE 1: AUDIT INSTRUMENT

TITLE: The development of validated guidelines that contribute to the prevention of malpractice litigation in nursing practice in South Africa.

Audit the malpractice litigation case and complete the following sections.

No---- (office use only)

The audit instrument

Section A: The Litigation (Questions 1-2)

1 Province

1	Gauteng	
2	ECP	

2 How was the court case presented?

1	In the High Court	
2	Settled out of Court	

SECTION B: DEMOGRAPHIC DATA OF THE PATIENT (Questions 3-11)

3 Age...

4 Gender

1	Female	
2	Male	

5 Marital status

1	Single	
2	Married	
3	Partner	
4	Widow /widower	
6	Divorced	

6 Dependents

1	None	
2	One	
3	Two	
4	Three	
5	>Three	
6	Not documented	

7 Any disability on admission

1	Yes	
2	No	

8 Indicate whether the patient had any of the following social habits

	Item	Yes	No	Not documented	NA (99) if a
1	Smoking				
2	Using unsolicited				
3	Alcohol				

9 Any underlying medical condition on admission e.g. hypertension

1	Yes	
2	No	
98	Not documented	

10 Choose one of the following: Employment at the time of admission to the hospital

1	Employed	
2	Self-employed	
3	Not employed	
4	Pensioner	
5	N/A e.g. child	

11 Choose one of the following: Type of employment

1	Professional, e.g. teacher, nurse, pilot, doctor	
2	Technical	
3	Businessman	
4	Administrative	
5	Tradesman	
6	Labourers / Unskilled	
7	Other	
8	99	

SECTION C: HOSPITALIZATION (Questions 12-31)

12 Indicate whether the nursing ward notes are available to audit

1	**Yes**	
2	**No**	

13 Indicate whether the nursing process documents were complete

1	Yes	
2	No	

14 Indicate the reason for admission

1	Elective surgery	
2	Planned treatment	
3	Emergency	
4	Ill /Sick requires medical	
5	Other	

15 Indicate the type of discipline (s) to which the patient was admitted before the adverse event

1	Cardiology	
2	Dermatology	
3	Gynaecology	
4	Medical	
5	Midwifery / Obstetrics	
6	Neonatology	
7	Nephrology	
8	Neurosurgery	
9	Neurology	
10	Orthopaedics	
11	Ophthalmology	
12	Paediatrics	
13	Psychiatry	
14	Trauma	
15	Urology	
16	Gen Surgery	
17	Cardiac surgery	
18	Other	

16 Indicate the type of ward / unit to which the patient was admitted before the adverse event

1	Emergency / Casualty	
2	General ward	
3	Paediatrics	
4	ICU	
5	Antenatal ward	
6	Labour	
7	Neonatology	
	OTHER	

17 Indicate whether the initial assessment including the fetus where applicable was:

1	Complete	
2	Incomplete	
3	Not done	

18 Indicate the status of the care plan of the patient: (Include all types of patients)

1	Complete	
2	Incomplete	
3	Not done	

19 Indicate whether the care plan was implemented?

1	Yes	
2	No	

20 Indicate whether special care plans were required

E.g. for a diabetic patient, patient in labour.

1	Yes	
2	No	

21 Indicate the status of the special care plan of the patient:

1	Complete	
2	Incomplete	
3	Not done	
4	N/A (99)	

22 If yes as indicated in question 23 indicate whether the special care plan was implemented.

1	Yes	
2	No	
3	NA (99)	

23 Indicate whether any of the following vital signs were monitored. (More than one response)

	Item	Complete (1)	Incomplete (2)	Not done	NA (99)
1	Blood pressure				
2	Pulse				
3	Foot pulses				
4	Fetal				
5	Respiration				
6	Temperature				
7	Intake and output				
8	Weight				
9	Neuro observations				
10	Post-spinal surgery				
11	Mental status				
12	Continuous ECG monitoring				
13	Continuous oxygen saturation Monitoring				
14	Other				

24 Indicate whether the following tests were done pre-adverse event where applicable

	Item	Yes (1)	No (2)	NA (99)
1	Haemoglucotest			
2	Haemoglobin			
3	Urine tests			
4	Urea and electrolytes			
5	Blood gasses			
6	Full blood count			
7	Liver functions			
8	Other			

25 Were the results of the tests interpreted?

1	Correctly interpreted by the Professional Nurse	
2	Incorrectly interpreted	
3	Not interpreted	

26 Were the results reported to the doctor?

1	Yes	
2	No	

27 If any diagnostic tests were done indicate whether action was taken based on the results

1	Yes	
2	No	
3	NA (99)	

28 Where applicable indicate whether the preoperative assessment for surgery was:

1	Complete	
2	Incomplete	
3	Not done	

29 Indicate whether the treatment / technique / management as prescribed was given

1	Yes	
2	No	

30 Do the patient's reports reflect the following about the patient? (More than one response)

	Item	**Complete (1)**	**Incomplete (2)**	**Not done**	**N/A 99**
1	Initial report				
2	Progress				
3	Correct interpretation of the clinical manifestations				
4	Interim report				
5	Reports to the doctor				
6	Discharge report				

31 If the patient was discharged indicate whether specific patient education was given

1	Yes	
2	No	

SECTION D OPERATING ROOM (Questions 32)

32 Indicate where applicable whether the following protocols in the operating room were adhered to:

	Item	Yes	No
1	Counting swabs		
2	Infection control		
3	Managing instruments		
4	Managing specimens		
5	Use of the diathermia		
6	"Surgical pause" or "Time out"		
7	Other		

SECTION E: ADVERSE EVENT(s) (Questions 33-37)

33 Indicate the environment where the adverse event(s) occurred

	Item	Yes
1	General ward	
2	ICU	
3	Operating room theatre	
4	Orthopedic ward	
5	Pediatric ward	
6	Neonatology unit	
7	Casualty / Trauma	
8	Labour	
9	Psych	
10	Other	

34 Describe the adverse event(s)

_____

_____

35. Indicate the patient outcome(s) as a result of the adverse event. (Could be more than one response)

	Item	Yes
1	Additional surgery	
2	Death	
3	Disabled	
4	Increased hospital stay	
5	Quality of life affected	

36 Healthcare profession(s) or non-healthcare professional responsible for adverse event

1	Nursing	
2	Medical	
3	Both nursing and medical	
4	Non-healthcare professional	
5	Both nursing and non-healthcare	
6	Other	

37 If nursing or both nursing and medical were chosen in question 38 indicate the category (ies) of nurses involved in the adverse event

1	Professional nurse	
2	Enrolled nurse	
3	Enrolled nursing assistant	
4	Midwife	

SECTION F: PRINCIPAL INCIDENT TYPE, SEVERITY OF ADVERSE EVENT AND FACTORS CONTRIBUTING TO THE ADVERSE EVENT (Questions 38-40)

38 Indicate the adverse event by Principal Incident type

1	Clinical management	
2	Human behavior problems	
3	Organisational	
4	Administrative	
5	Other	

39. Indicate the severity of the adverse event according to the Safety Assessment Code Matrix (SAC) (SA Health Risk Management Framework, nd)

1	Extreme	
2	Major	
3	Moderate	
4	Minor	
5	Insignificant	

40 Indicate which of the following FACTORS contributed to the adverse event. In this question there could be more than one answer

1	Clinical manifestations not	
2	Poor monitoring	
3	Failing to apply guidelines/	
4	Failing to give treatment as	
5	Incorrect treatment	
6	Accumulation of omissions	
7	Accumulation of errors	
8	System failures	
9	Behavioral e.g. attitude	
10	Lack of Supervision	
11	Lack of training	
12	Lack of knowledge	
13	Other	

End of Audit instrument

Luleka Gcawu

ANNEXURE 2: ETHICS APPROVAL HREC

Approved with Stipulations

20-Apr-2017
GCAWU, LULEKA LP
Ethics Reference #: N16/02/027A

Title: The development of validated guidelines that contribute to the prevention of malpractice litigation in Nursing practice: in South Africa.

Dear Miss LULEKA GCAWU,

The New Application received on 17-Mar-2017, was reviewed by Health Research Ethics Committee 1 via Committee Review procedures on 05-Apr-2017. Please note the following information about your approved research protocol:

Protocol Approval Period: 05-Apr-2017 -04-Apr-2018
Present Committee Members:

Weber, Franklin CFS
Sprenkels, Marie-Louise MHE
Els, Petrus PJJS
Lachman, Anusha A
Barsdorf, Nicola N
Whitelaw, David DA
Decloedt, Eric EH Hall, David DR
Glashoff, Richard RH
Manuel, Ashwin AS
Mbhenyane, Xikombiso XG
Werely, Cedric CJ
Burgess, Lesley

The Stipulations of your ethics approval are as follows:

1. The researcher should provide the ethics committee with evidence that the custodians of the information have given permission to access the reports.

Please remember to use your protocol number (N16/02/027A) on any documents or correspondence with the HREC concerning your research protocol. Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principals for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principals Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western

Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital

manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research. For standard HREC forms and documents please visit: www.sun.ac.za/rds. If you have any questions or need further assistance, please contact the HREC office at.

Included Documents:

- Revised title GCAWU DECLARATION- 09'10'16.pdf
- Final GCAWU PROPOSAL- 12.03.17 (1).docx
- Revised title Declaration Supervisor E Stellenberg.pdf
- Revised title Prof Stuart Whitaker Co-supervisor 20150224 Investigators Declaration V4 2 (Eng).docx Revised Checklist Ethics.doc
- Revised title GCAU ETHICS APPLICATION FORMS.pdf Abbreviated CV Co_Supervisor Prof Stuart Whittaker .pdf
- L Gcawu SYNOPSIS for ethics 15 Mar 17.docx
- Abbreviated CV Oct 2016 PROF ETHELWYNN L STELLENBERG.pdf
- GCAU WAIVER OF CONSENT - 09.10.16.pdf GCAWU CV 25 10 16.doc
- RE Ethics documentation for PhD student L GCAWU.msg Final GCAWU PROPOSAL-12.03.17 (1).docx
- LULEKA GCAWU - INSTRUMENT.docx

Sincerely,
Franklin Weber
HREC Coordinator
Health Research Ethics Committee 1

Investigator Responsibilities

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1. Conducting the Research. You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.
2. Participant Enrolment. You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.
3. Informed Consent. You are responsible for obtaining and documenting effective informed consent using only the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.
4. Continuing Review. The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is no grace period. Prior to the date on which the HREC approval of the research expires, it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur. If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.
5. Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You may not initiate any amendments or changes to your research without first obtaining written HREC review and approval. The only exception is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.
6. Adverse or Unanticipated Events. Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within five (5) days of discovery of the incident. You must also report any instances

of serious or continuing problems, or non-compliance with the HRECs requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch University Health Research Ethics Committee Standard Operating Procedures www.sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.

7. Research Record Keeping. You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC
8. Reports to the MCC and Sponsor. When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.
9. Provision of Emergency Medical Care. When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.
10. Final reports. When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.
11. On-Site Evaluations, MCC Inspections, or Audits. If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.

ANNEXURE 3: EASTERN CAPE PERMISSION LETTERS

Province of the
EASTERN CAPE
HEALTH

LEGAL SERVICES DIRECTORATE
Room 7 • 1st Floor • Unathi House • Siwani Avenue • Bhisho • Eastern Cape
Private Bag X0038 • Bhisho • 5605 • REPUBLIC OF SOUTH AFRICA
Tel.: +27 (0)40 608 1529 • Fax: +27 (0)40 609 8101/9 • Email: nontuthuzelo.ngqwane@echealth.gov.za

INTERNAL ROUTE SHEET

CHIEF DIRECTORATE: CORPORATE SERVICES
DIRECTORATE: LEGAL SERVICES

SUBJECT: MEMORANDUM FOR AUTHORITY FOR ACCESS TO INFORMATION TO ASSIST WITH THE DEVELOPMENT TO THE PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE IN SOUTH AFRICA

NO.	ROUTE	NAME	SIGNATURE	COMMENTS	DATE
1.	Senior Manager: Legal Services	Mr. MLA Mlambo			27 September 2017
2.	Superintendent General	Dr. TD Mbengashe			10/10/2017

Compiler: N Ngqwane
Ext: 0406081529

Received By: NOMSA
Time: 11h20
Date: 2017/09/29
Tel: 040 608 0000 Fax: 040 000 0000
Office of the Superintendent General

Together, moving the health system forward

Fraud prevention line: 0800 701 701

Province of the
EASTERN CAPE
HEALTH

Office of the Senior Manager: Legal Services Directorate
Room 7 • 1st Floor • Unathi House • Siwani Avenue • Bhisho • Eastern Cape
Private Bag X0038 • Bhisho • 5605 • REPUBLIC OF SOUTH AFRICA
Tel.: +27 (0)40 608 1529 • Fax: +27 (0)40 609 8101/9 • Website: www.ecdoh.gov.za

INTERNAL MEMORANDUM

TO:	**DR. T.D. MBENGASHE** **SUPERINTENDENT GENERAL**
FROM:	**MR. MLA. MLAMBO** **SENIOR MANAGER: LEGAL SERVICES**
SUBJECT:	**MEMORANDUM FOR AUTHORITY FOR ACCESS TO INFORMATION TO ASSIST WITH THE DEVELOPMENT TO THE PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE IN SOUTH AFRICA**

PURPOSE

The purpose of this memorandum is to:

1. Advise the Superintendent General of sought authority for Ms. L. Gcawu to be granted authority to access contents and records of file within State Attorneys to be able to collate information from that will be used to do research.

2. Signing of attached letter of authority addressed to the Chief Litigation Officer and State Attorneys for the Superintendent General.

BACKGROUND

Ms. Gcawu is employed by the Department and is partaking on research that is intended to assist the Department.

In order to effectively conduct this research, it will be required of her to access the file held by the State Attorney, Port Elizabeth, East London and Mthatha to obtain as much as possible information.

Therefore this draft letter of authority is required to be presented by her to the State Attorneys upon her visit and the State Attorney will not release or allow her to access such without the authorization of the Department and conditions attached.

FINANCIAL IMPLICATION

No financial implication to arise in this regard.

RECOMMENDATION

It is hereby requested that the request is noted and that the draft to the Department of Justice (Chief Litigation Officer).

MR. M.L. MLAMBO
SENIOR MANAGER: LEGAL SERVICES

27/09/2017.
DATE

APPROVED / NOT APPROVED

DR. T. D. MBENGASHE
SUPERINTENDENT GENERAL

10/10/2017
DATE

Province of the
EASTERN CAPE
HEALTH

Office of the Senior Manager: Legal Services
Room 7 • 1st Floor • Unathi House • Siwani Avenue • Bhisho • Eastern Cape
Private Bag X0038 • Bhisho • 5605 • REPUBLIC OF SOUTH AFRICA
Tel.: +27 (0)40 608 1529 • Fax: +27 (0)40 609 8101/9 • Website: www.ecdoh.gov.za

Our ref: Mr. Mlambo/ncn/ **Your ref:**

Ms. D. Phahlane
Chief Litigation Officer
Department of Justice and Constitutional Development
PRETORIA

Dear Madam;

RE: LETTER OF AUTHORITY TO THE STATE ATTORNEYS OFFICE: RE THE DEVELOPMENT OF VALIDATED GUIDELINES TO PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE

1. This serves to confirm and grant the authority that the Department has authorized Ms. L. Gcawu to have access to all the files held by the State Attorneys in defending such claims as this information is sought in order to conduct abovementioned research in terms of the attached letter and a subsequent conditions.

2. This letter of authorization is only valid for 3 months from date of signature of the HOD.

3. The terms and conditions applicable in terms of the Eastern Cape Health Research Committee remains applicable in this regard and therefore the information obtained whilst conducting research may not be used for any other purpose other than of the reasons requested hereto.

Yours faithfully

Dr. T.D. Mbengashe
Superintendent General
Date: 10/10/2017

Eastern Cape Department of Health

Enquiries:	Madoda Xokwe	Tel No:	040 608 0710
Date:	25 August 2017	Fax No:	043 642 1409
e-mail address:	madoda.xokwe@echealth.gov.za		

Dear Ms. L. Gcawu

Re: The Development of Validated Guidelines That Contribute to the Prevention of Malpractice Litigation in Nursing Practice in South Africa (EC_2017RP12_126)

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

PGDP EASTERN CAPE 2004 2014

Ikamva eliqaqambileyo!

0436421409

Dear Ms. L. Gcawu

Malpractice Litigation in Nursing practice Re: The Development of Validated Guidelines That Contribute to the Prevention of in South Africa (EC_2017RP12_126)

The Department of Health would like to inform you that your application for conducting a research on the above mentioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicate above

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

ANNEXURE 4: PERMISSION LETTER FROM THE GAUTENG DEPARTMENT OF HEALTH RESEARCH COMITEE

EASTERN CAPE PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

OUTCOME OF PROVINCIAL PROTOCOL REVIEW COMMITTEE (PPRC)

Researcher's Name (PI)	Ms Gcawu Luleka
Organization I Institution	Stellenbosch University
Research Title	The development of validated guidelines that contribute to the prevention of malpractice litigation in Nursing practice in South Africa
Contact number	083 693 8900
Protocol number/Proposal number	GP 2027 RP 23 153
Sites	State attorneys' offices in Eastern Cape province

Your application to conduct the abovementioned research has been reviewed by the Province and permission has been granted.

We request that you submit a report after completion of your study and present your findings to the Gauteng Health Department.

Yes Permission granted

Permission denied

Recommended by

MS Yvonne SKosana
Acting Chairperson
Date •

ANNEXURE 5: ACTING CHIEF LITIGATION OFFICER: DEPARTMENT OF JUSTICE & CONSTITUTIONAL DEVELOPMENT

From:	Luleka Gcawu
To:	Stellenberg, EL, Prof [elstel@sun.ac.za]
Subject:	Fwd: FW: Data collection documents
Date:	Sunday, 29 September 2019 9:18:40 PM
Attachments:	GCAWU LETTER FROM ETHICS COMITTEE.pdf LULEKA GCAWU - INSTRUMENT= DATA COLLECTION.docx Research Permission letter for Ms L Gcawu.pdf

---

Receive the email from Mr Isaacs

---------- Forwarded message ---------
From: **Isaacs Rodney** <RoIsaacs@justice.gov.za> Date: Fri, May 18, 2018 at 8:45 AM
Subject: FW: Data collection documents
To: Lekabe Kgosi <KLekabe@justice.gov.za>, Phahlane Mohube <MPhahlane@justice.gov.za>, Botes Sybrand <SBotes@justice.gov.za>
Cc: Luleka Gcawu (luleka.gcawu@gmail.com) <luleka.gcawu@gmail.com>

Dear Colleagues

Will you take note of the request and authorization letters from the Applicant. Please be so kind to assist the applicant when she does contact your o f f i c e .

Regards

Rodney Isaacs
Acting Chief Litigation Officer

Department of Justice & Constitutional Development SALU BUILDING, Room 2110

Tel: (012) 406 -4780/83
© 082 305 4463
Email: RoIsaacs@justice.gov.za

From: Luleka Gcawu [mailto: luleka.gcawu@gmail.com]
Sent: 18 May 2018 08:36 AM
To: Phahlane Mohube; Isaacs Rodney
Subject: Fwd: Data collection documents

Good morning Ms Pahlane and Mr Isaacs Kindly find the attached documents.
Ms Gcawu

---------- Forwarded message ---------
From: Luleka Gcawu <luleka.gcawu@gmail.com>
Date: Thu, 12 Apr 2018, 12:37 PM
Subject: Data collection documents
To: <tnengwekhulu@justice.gov.za>

Afternoon Sir

Kindly receive the attached documents as requested.
Ms L. Gcawu

Privileged/Confidential information may be contained in this message. If you are not the addressee indicated in this message (or responsible for delivery of the message to such person) you may not copy or deliver this message to anyone. In such case, you should destroy this message and kindly notify the sender by reply E-Mail. Please advise immediately if you or your employer do not consent to e-mail messages of this kind.
Opinions, conclusions and other information in this message that do not relate to the official business of the Department of Justice and Constitutional Development shall be

understood as neither given nor endorsed by it. All views expressed herein are the views of the author and do not reflect the views of the Department of Justice unless specifically stated otherwise.

ANNEXURE 6: HREC ETHICS RENEWAL LETTER

Approved with Stipulations

Progress Report

12/09/2018

Project Reference #: 4424

Ethics Reference #: N16/02/027A

Title: The development of validated guidelines that contribute to the prevention of malpractice litigation in Nursing practice in South Africa.

Dear Miss Luleka Gcawu,

Your request for extension/annual renewal of ethics approval dated 22/08/2018 10:28 refers.

The Health Research Ethics Committee reviewed and approved the annual progress report you submitted through an expedited review process. The progress report was approved with the following **stipulations**:

Kindly note that your application is late and should have been submitted before the ethics expiry date. You are reminded that you need permission from the Health Research Ethics Committee (HREC) to use any information/samples collected after the expiry date.

The approval of this project is extended for a further year.

Approval date: 12 September 2018

Expiry date: 11 September 2019

Kindly be reminded to submit progress reports two (2) months before expiry date.

Where to submit any documentation

Kindly note that the HREC uses an electronic ethics review management system, Infonetica, to manage ethics applications and ethics review process. To submit any documentation to HREC, please click on the following link: https://applyethics.sun.ac.za.

Please remember to use your **Project ID** [4424] and Ethics Reference Number N16/02/027A on any documents or correspondence with the HREC concerning your research protocol.

National Health Research Ethics Council (NHREC) Registration Numbers: REC-130408-012 for HREC1 and REC-230208-010 for HREC2

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005240 for HREC1

Institutional Review Board (IRB) Number: IRB0005239 for HREC2

The Health Research Ethics Committee complies with the SA National Health Act No. 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principals for research, established by the Declaration of Helsinki and the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principals, Structures and Processes 2015 (Department of Health).

Yours sincerely,

Mrs. Ashleen Fortuin

Health Research Ethics Committee 1

ANNEXURE 7: ROUND 1 DELPHI METHOD QUESTIONNAIRE

DELPHI METHOD: ROUND ONE QUESTIONNAIRE

Title: Development of validated guidelines that will contribute to the prevention of malpractice litigation in Nursing practice in South Africa

1. Introduction

The researcher is a PHD student at Stellenbosch University and one of the researchers who is participating in a larger study "Retrospective Audit Analysis of Malpractice Litigation Cases in Nursing practice in South Africa" in which malpractice litigation in Nursing practice is being investigated in South Africa (N16/02/027).

2 Background to the main study

The main study included three students; two master's degree and a PhD student. The masters' degree students completed an investigation into malpractice litigation in nursing practice in the private healthcare sector and the PhD student an investigation in malpractice litigation in nursing practice in the public sector. The aim of the study was to conduct a retrospective audit on malpractice litigation cases involving nursing practitioners, which compromised the quality and safety of patient care.

The study is a descriptive retrospective study that examined factors related to malpractice cases served in court or settled out of court. The statistician completed a power analysis to determine the number of cases required for the study. It was decided that 400 cases were required, of which 200 to be completed in the private healthcare sector and 200 in the public healthcare sector. The Eastern Cape and Gauteng provinces were chosen because most litigation cases pending in South Africa are in these provinces. The Public Health Sector in Gauteng faced negligence claims in health amounting to R1.28 billion for the years 2012-2013 the highest in the country, with Eastern Cape following facing claims of R876-million for the same period (Child, 2014).

One hundred twenty-two cases (61%) of the 200 planned cases for the private healthcare were audited from the private sector and 203 from the public sector (101.5%). In addition, the audited cases were drawn from cases which occurred over a period of eleven years (2006-2016) in these provinces.

The data collection was conducted in legal firm's offices in the private sector and state attorney's offices in public sector.

A pilot study consisting of an opportunistic sample of 42 malpractice cases either served in court or settled out of court was conducted to evaluate and refine the study methodology.

The study objectives of the main study are:

- To categorise the incident types and determine the factors associated with adverse events involving nursing practitioners that have resulted in malpractice litigation.
- To identify other members of the health service team that are associated with the adverse events that resulted in malpractice litigation.
- To assess the severity of the adverse events associated with malpractice litigation.
- To formulate validated guidelines and solutions that have the potential to reduce the incidence of malpractice

The data analysis was done applying SPSS version 25 software. All ethical considerations were adhered to.

3 Background to the study conducted by the PhD student

This study is a sub study of the main study as described above. A brief summary is described below. The title is the "Development of validated guidelines that contribute to the prevention of malpractice litigation in Nursing practice in South Africa". The study was conducted in three phases. The methodology as applied in each phase is briefly described.

Phase 1. A retrospective audit of adverse events that led to malpractice litigation in the public healthcare sector was conducted in the Gauteng and Eastern Cape provinces. The researcher audited 98 trial bundles in Gauteng and 105 trial bundles in the Eastern Cape provinces, with a total N=203. practice in the public health care sector in Gauteng and Eastern Cape provinces.

Phase 2. The data obtained from the private and public healthcare sectors were merged and a statistical comparative analysis applying the SPSS were completed.

Phase 3. Based on the analysis of the outcome of objective 2 draft guidelines were developed which is now in the process of being validated by applying the Delphi method.

3.1 The objectives set for the study were developed by the lead researcher of the main study, which included:

1. an analysis of adverse events through a retrospective audit of the malpractice litigation trial bundles in the public health care sector in the Gauteng and Eastern Cape provinces

2. a statistical comparative analysis of adverse events that led to malpractice litigation in the private health care sector in Gauteng and Western Cape provinces and in the public health care sector in Gauteng and Eastern Cape provinces.
3. the development of nursing guidelines which will contribute to the prevention of malpractice litigation in nursing practice based on the comparative analysis of the descriptive survey and analysis of adverse events which lead to malpractice litigation as described in objective 2.
4. a validation process of the developed which will contribute to the prevention of malpractice litigation in nursing practice by applying the Delphi method.

The data collection was conducted in state attorney's offices in the Eastern Cape and Gauteng Cape provinces. The data analysis was done with the assistance of the biostatistician applying SPSS version 25 software. All ethical considerations were adhered to.

3.2 Brief overview of the results:

A total of 325 trial bundles were audited, 81.3% completed rate of the 400 cases as envisaged for this study. The study has identified high-risk areas prone to adverse events that require urgent attention. In the public healthcare sector most cases audited n=143 (70.4%) of N=203 were because of negligence in labour wards of which 135 (94.4%) cases were cerebral palsies.

3.2.1 Aspects about the nursing process

- Patients not assessed n=31(9.5%) or incompletely assessed n=175 (53.8%).
- Care plans were incompletely formulated n=155 (47.7%) or not done n=49(15.1%)
- Discharge reports not done n=204 (62.8%).

3.2.2 The adverse events categorised according to principal type. The results identified the following:

- Clinical management n=291(89.5%)
- Human behaviour n=98(30.2%)
- Organisational n=77(23.7%)
- Administrative n=21(6.5%)

3.2.3 Factors that contributed to the adverse events resulting in malpractice litigation in nursing practice.

The following were identified:

- failing to apply guidelines / protocols n= 297 (91.4 %)

- poor monitoring n=240 (73.8 %),
- clinical manifestation not responded to n=238(73.2 %)
- accumulation of errors n=136 (41.8 %).
- lack of knowledge n=94 (28.9 %),
- behavioural n=86 (26.5 %),
- system failure n=70 (21.5 %),
- lack of training n=63 (19.4 %) were also the factors that contributed to adverse events in this study
- failing to give treatment as required and accumulation of omissions had equal distribution of n=162 (49.8 %).

3.2.4 Substandard care in specialised clinical areas

The study further revealed that where specialised care was offered substandard care was given which resulted in adverse events. The special care plans n=151(46.5%) were incomplete and n=26 (8.0%) of the patients had no special care plans formulated.

The special care plans implemented n=176 (54.2%) and n=71 (21.8%) were not implemented although there was a need to implement.

The majority of the adverse events occurred in the labour ward, n=158(48.6%), followed by general wards n=38 (11.7%), the operating theatre room n=24 (7.4%) and ICU n=22 (6.8 %).

3.2.5 The outcome of the adverse events revealed:

The majority of patients n=232 (71.4%) required increased hospital stay due to the adverse events, n=247 (76.0%) had their quality of life affected, n=175 (53.8%) were disabled, n=85 (26.2%) required additional surgery and n=29(8.9%) died.

3.2.6 Health care professionals responsible for the adverse events were:

Both nursing staff and medical staff contributed to n= 197 (60.6 %) of adverse events, nursing staff alone n=81 (24.9 %) and medical staff n=30 (9.3 %). The nurse category mostly involved in the occurrence of adverse events as confirmed by the trial bundles audited were midwives n=164 (43.4%), followed by professional nurses n=128 (33.9%), n=51 (13.5%) enrolled nurses and enrolled nurse n=35 (9.3).

The PhD student is now in the final phase (phase 3) of the study and that is to validate the developed draft guidelines.

4 Invitation to participate in the study

Against this background and due to your expertise in safe quality patient care, you are invited to participate in a Delphi process to validate the draft set of nursing practice guidelines aimed to reduce the incidence of adverse events in nursing practice in South Africa.

By agreeing to participate, it will be regarded as giving informed consent based on the explanation given about the study. This research study obtained ethics approval from:

- Stellenbosch University (N16/02/027A),
- Eastern Cape Health Research Committee reference number (EC_2017RP12_126).
- Head of Legal Services Eastern Cape Department of Health and the Head of the State Attorney's Offices.
- Gauteng Department of Health Provincial Protocol Review Committee reference number (GP2027R23153).
- Head of the State Attorney's Offices South Africa.

Participating in this study is voluntary but you may also decline from participating in the study. However, should you decide to participate; it will be important for you to participate in all the rounds until a consensus have been reached among the participants. No payment or reward will be granted for your participation.

The purpose of this questionnaire is to request your participation in a process to validate draft guidelines that will contribute to the prevention of malpractice litigation in nursing practice in South Africa by applying the Delphi Technique.

The researcher developed the guidelines based on the literature and specifically the theoretical framework that guided this study, International classification for patient safety (WHO, 2009:1-154) and The Generic Reference Model (GRM) (Runciman et al., 2006: 6) and the results of the research study conducted in private and the public sectors.

The guidelines were developed according to the WHO guideline development process (WHO, 2012:4). The validation process will continue until consensus about the guidelines between the participants are reached. Due to a possible lengthy process, the researcher will appreciate it if the turnaround time could be three (3) days after receiving the questionnaire. You may contact me for any clarity or my supervisors at the telephone numbers or email addresses as listed below:

Your support in this regard will indeed be appreciated.

Luleka Gcwau

PhD student SU 15263096 (Stellenbosch University): Cell: 0836938900: email:luleka.gcawu@gmail.com

Supervisor: Prof Ethelwynn L Stellenberg: Office: 0219389297 email: elstel@sun.ac.za

Co-supervisor: Prof Stuart Whittaker: Cell: 0834506889 / email: stuart@mqh.co.za

5. Instructions to Delphi validation participants

- The questionnaire consists of 19 pages and will take approximately 1 hour to complete.
- Please provide your recommendations and comments in the space provided.

THE PROPOSED QUESTIONNAIRE: DEVELOPED DRAFT GUIDELINES FOR VALIDATION

SECTION A: DEMOGRAPHIC PROFILE OF DELPHI PARTICIPANTS

1. Indicate your professional category

1	Registered Nurse	
2	Registered Medical Doctor	
3	Registered Pharmacist	
4	Other (please specify)	

2. Indicate your highest professional qualification

1	Masters	
2	Doctorate	

3. Indicate your clinical speciality area

1	Medical	
2	Midwifery	
3	Neonatology	
4.	Nephrology	
5	Neurology	
6	Ophthalmology	
7.	Orthopaedics	
8	Paediatrics	
9	Psychology	
10	Surgical	
11	Trauma	
12	Urology	
13	Public health	
14	Obstetrics	
15	Other (specify)	
99	Not applicable	

4. This question may have a multi response answer. Indicate your participation in each area of the following.

1	Academic in healthcare	
2	Consultant in health systems	
3	Participate in accreditation of hospitals	
4	Participating in policymaking in healthcare	
5	Participating in regulating bodies in healthcare	
6	Writing healthcare standards for health establishments	
7	Clinical practice	
8	Other	

SECTION B. CLINICAL MANAGEMENT: PHASES OF THE NURSING PROCESS:

5. PHASE 1 OF THE NURSING PROCESS: SUBJECTIVE INFORMATION

Recommended drafted guidelines	**Agree (1)**	**Disagree (2)**	**COMMENT**	
5A. The nurse should have the required knowledge and understanding of the phases of the nursing process.				
1.The knowledge pertaining to the phases of the nursing process can be assessed by doing a pre-test before the in-service training is conducted and a post-test at the beginning of the workshop				
2. The nurse should collect the patient ‘s subjective data (demographic, personal and social data) during assessment namely:				
2.1.Age of the patient				
2.2.Gender				

2.3.Marital status				
2.4. Dependents				
2.5.Disability on admission				
3.Social habits which include:				
3.1 Smoking				
3.2. Use of alcohol				
3.3. Use of unsolicited drugs				
5 (B). A comprehensive medical and family history taking should be done to all patients as it stated by the scope of practice for nurses (R2598 of 1984)				

6. PHASE 1 : OBJECTIVE

Recommended drafted guidelines	Agree (1)	Disagree (2)	COMMENT
6 (A).The nurse should collect the patient 's objective data during assessment which include vital signs and other special tests below depending on the patient's condition and where applicable			
1. Blood pressure			
2. Pulse			
3.Temperature			
4. Respirations			
5.Foetal heart Monitoring			
6. Foot pulse monitoring			
7.Continuous ECG monitoring			
8. Oxygen saturations			
9.Post spinal surgery			
10.Circulation checks post plaster of Paris insertion			
11. Neuro observations			

6 (B). The special tests should be done and these form part of assessment			
1.Haemoglobin			
2. Haemoglucotest			
3. Urinalysis			
4. Weight			
5. Intake and output			
6. Height			
6 (C).The nurse should be able to conduct a physical assessment of the patient which include :			
1. Examination of the body, head to toe checking for any abnormalities, bruises, discolouration, any disfigurement, pressure sores, signs of dehydration			
6BThe specialist nurse should perform heart and lung auscultation			

7. PHASE 2 OF THE NURSING PROCESS: FORMULATING A NURSING DIAGNOSIS

Recommended drafted guidelines	Agree (1)	Disagree (2)	COMMENTS
The nurse should be able to analyse all data collected during the assessment phase, interpret it and formulate a nursing diagnosis.			
1. Interpret the subjective statements from the patient			
2.Interpretation the patient's mental and emotional status			
3.Interpret the data obtained from physical assessment			
To formulate the correct nursing diagnosis the nurse should understand the following :			

1.Normal and abnormal ranges of the vital signs			
2. Normal and abnormal ranges of the tests that are done on the patients			
3. Interpret the data obtained from physical assessment			
4.Normal and abnormal ranges of the special tests done			

8. PHASE 3: PLANNING

Recommended drafted guidelines	**Agree (1)**	**Disagree (2)**	**COMMENTS**
1.The nurse should understand how to set the nursing interventions and outcomes			
2.The nursing care plans should be set such that they are achievable and measurable			
3. The multidisciplinary team has to be included during this stage of which the scope of practice is taken into consideration.			
4. The nurse should set the long and short term goals and each goal should have an expected outcome.			
5. This stage depends on the nursing diagnoses that is formulated and the patient's needs should be prioritised using Maslow's hierarchy of needs.			
6. The special care plans are also formulated during this stage to manage patients with special needs such as woman in labour, woman who are diabetic.			
7.The nursing care plans should be written clearly on the patient 's			

nursing process records so that they are accessible to other health professionals			

8. PHASE 4: IMPLEMENTATION

Recommended drafted guidelines	Agree (1)	Disagree (2)	COMMENT
1. The care plans are implemented in this stage during which a nurse carries out the care plans that were formulated in phase 3			
2. The nurse should conduct nursing care activities and these should be guided by the availability of skills, knowledge and scope of practice			
3. Patient treatment techniques that were prescribed in phase 3 are executed in this stage			
4. The nurse should adhere to protocols, guidelines and standards that are laid down by the institution, governing body and employer.			

9. PHASE 5: EVALUATION

Recommended drafted guidelines	Agree (1)	Disagree (2)	COMMENT
1. This is a stage where a nurse continuously evaluates the effectiveness of the nursing care activities documented in the implementation and planning stages.			
2. The nurse then modifies the care plan as needed.			
3. If the patient‘s condition has not improved the scientific nursing process is recommenced from stage 1 to stage 5.			

10A: PHASE 6: DOCUMENTATION

Recommended drafted guidelines	**Agree (1)**	**Disagree (2)**	**COMMENT**
1**. Documentation should be included as the last phase in the nursing process so that there can be improved documentation of patient's information.**			
10A. Documentation should meet the acceptable principals of documentation specifically:			
1. Clear documentation that is precise to the point			
2. Signature and designation of the person that was documenting should be clear			
3. Date and time should always appear in the patient's records			
4. Correction ink should not be used in patients' documents			
10(b). The patient's report should be written completely which follows the stages of the nursing process:			
1.Initial report			
2.Progress reports			
3.Interim reports			
4.Transfer reports			
5.Crisis report			
6. Death report			
7.Discharge reports			
8. Discharge reports should indicate patient education given			

11. SECTION C: HUMAN BEHAVIOURAL PROBLEM

RECOMMENDATION	Agree (1)	Disagree (2)	Comment
11a. Health care professionals' behavioural problems may be addressed by nursing management as follows:			
1. Ensuring that a HE nursing philosophy is in place which is discussed periodically for reinforcement.			
2. Encouragement of good moral behaviour amongst the nurses.			
3. Positive behaviour amongst HE managers may result in quality care being delivered, reduced patient complaints and satisfied patients.			
4. Ensuring that there is openness , transparency , honesty, professional values amongst the health care professionals in the HE			
5. Ensuring that there is continuous staff motivation so that staff demotivation is reduced.			
6. Introduction of a just culture environment in the HE to promote the need for an open and honest reporting system within a quality learning environment.			
7. Attending to the factors that can negatively affect the staff behaviours such as staff shortage, work overload, favouritism, compulsory overtime, conflicts			
8. Introduce an environment that is non punitive but corrective			
9. Implementing a 'just culture' in event management, the contributing organisational and environmental factors are identified, as well as the nurses' responsibility and accountability			
10. A culture of trust, reporting, transparency and discipline are needed for the delivery of safe, quality patient care.			

11. Introduce and implement disciplinary measures where it is necessary.			
12. Introduce a grievance procedure.			
13.Introduce a performance appraisal programme to award the best performing staff members			
14. Establishment and strengthening debriefing centres in the HE such as staff counselling centres, Employee Assistant Programmes, clinical psychology and team building committees			
15. Conduct climate meetings whereby each staff member will feel free to voice without fear, concerns without fear of discrimination and victimization			
16. Establish a strengthened relationship with relevant stakeholders.			
17. Establish a good relationship between the Nursing education institutions and hospitals. The relationship will assist with standardisation of nursing practices and assist the when mentoring nursing students and team building.			

12. SECTION D. ORGANISATIONAL FACTORS

Recommended drafted guidelines	**Agree (1)**	**Disagree (2)**	**COMMENT**
12 (A) The HE should ensure that there is effective leadership, active collaboration and good governance HE establishments by :			
1. Ensuring that quality assurance department and in service education departments work together to identify the and address the knowledge gaps			
2.Establishment of committees such as quality assurance			

committee, research committee , in service education committees, budget committee, health and safety committee, skills development committee and audit committee and each department should be represented			
3.Ensure that the committees are resourced and functional			
4. Proper planning and organisation in HE can contribute to the prevention of provision of substandard care.			
5. Development of strategic plans, institutional year plans, unit year plans that will guide the nursing care activities.			
6. Ensuring that there is proper staffing norms and the staff is allocated according to the needs of each department			
7. Ensure that budgeting is in line with the Public Finance Management Act and the needs of the clinical area.			
8. Prioritising adequate human and material resources			
9.Ensuring that there is enough budget to appoint new staff members to overcome staff shortage that may lead to adverse events is critical			
10. Employment of effective recruitment and retention strategies.			

11. Budget allocation for staff development.			
12. Establishment of cost containment committees that will ensure proper financial management and attending to priority needs of the HE.			
13.Development and implementation of structure standards, process standards and outcome standards			
14. Implement patients' rights charter whereby patients' rights are respected and not violated in the HE.			
15. Ensuring that the vision and mission statement should give guidance to service delivery			
16. Ensuring that there is an infection control department.			
17. Ensuring that the disaster management plan is in place			
18. Ensuring that risk management plan should be in place and the staff should be knowledgeable on how to manage analyse and risk			
19. An effective communication system whereby patients and staff members are well informed should be in place			
20. Ensuring that the facilities and infrastructure are maintained and well equipped such that they meet the applicable regulations			

21. Establishment of a good relationship between the Nursing education institutions and hospitals. The relationship will assist with standardisation of nursing practices and assist when mentoring nursing students.			
23. Ensuring that community involvement is strengthened in HE management system			
24. There should be proper selection criteria for staff members before employment especially those that are in management positions			
25. Management skills and styles need to be properly explored to avoid selecting managers who lack management skills as this may lead to poor management and substandard care being provided in HE			
26.A multidisciplinary approach should be applied to ensure an efficient and effective HE organisation			

12. NURSING LEADERSHIP AND MANAGEMENT

RECOMMENDATION	AGREE (1)	DISAGREE (2)	Comments
12 (B). Mentoring and Coaching			
1. Ensuring increased continuous mentoring and Coaching within the work			

environment will increase job security.			
2. Coaching should be done with supervision and be provided in a non-threatening, noninterfering manner.			
3. Introduce mentors to couch and support the newly employed nurses, student nurses and those that have been employed for a long time. Each ward/unit should have its own mentor that is responsible to mentor the newly appointed staff and students. This will instil confidence and productivity in their work. In addition, this will provide opportunities for staff members to ventilate their feelings and fears.			
4.Offer induction and orientation for newly appointed staff members at least for the first 2 weeks after appointment			
5. Continuous Coaching and supervision will allow the senior nursing practitioner to identify the current level of competency with which duties are executed.			

Recommended drafted guidelines	Agree (1)	Disagree (2)	Comments
12C. **Operational management**: The wards / units in HE should ensure that there is implementation of HE operational plans and can be done by ensuring that:			
1. institutional plans are implemented and the unit operational plans are in line with those of the HE			
2. there is enough supply of equipment and these are in good working order			
3. The measures to control infection are in place and the staff is well informed about these measures			
4. Ensure that stock supply and control is done			
5.Treatment techniques are implemented			
6.There is unit team building			
7.There is staff development			
8.Proper organisation and planning			
9.There is proper work allocation and distribution of work according to scope of practice			
10. Patient safety measures are in place such as infection control measures, cleanliness.			
11.The operational standards are implemented guided by			

guidelines, policies, acts and regulations			
12.Management by objectives, in-service training and clinical demonstrations can be used as unit/ ward measures for staff development			
13.Risk management, disaster management are in place			
14.Conflict management is in place			

12D. Continuous nursing professional development (CPD)

RECOMMENDATION	Agree (1)	Disagree (2)	Comment
1. Identify knowledge gaps in each HE by conducting small surveys and clinical audits.			
2. Encourage staff members to identify the areas they do not feel competent in			
3. Introduce a scheduled programme for in-service and informal training at hospital level.			
4.Identify topics that will be offered on weekly basis and those that will be offered on 6 months' basis			
5. Informal training can be implemented by making use of the morning meeting session, using posters and			

pictures to engage all learning strategies.			
6. Prioritise the topics that have to be included in the HE in service education programme based on the identified needs.			
7.Send staff members to seminars, conferences and workshops			
8. Encourage staff members to register for formal education at colleges and universities.			
9.Incorporation of adverse events and malpractice litigation in Nursing Education Institutions curricula			
10.Identified knowledge gap should be bridged by doing refresher courses			
11. In-service education department should ensure implementation of the in service education programmes Management by objective , Clinical demonstrations			
12. Refresher course at least six monthly in the Health Establishment on the following:			
1. Anatomy and physiology			
2. Pathophysiology of the most common diseases			

3. Management of pathological conditions		
4. Medication indication , contraindications, side effect , effects , action , route and dosage		
5.Control of drugs		
6. Establish opportunities where nursing personnel can be made aware of the adverse events as well as the near misses within the organization and how these gaps are negatively affecting the quality and safety of patient care. The nurses should be given in service education on how to analyse the adverse events and write reports on this. The preventive measures are on adverse events are to be taught as well.		

12E. Nursing Monitoring and evaluation

RECOMMENDATION	Agree (1)	Disagree (2)	Comment
12. (E). Clinical audits			
Conduct clinical audits and check if the following are done as per guidelines, policies and regulations :			
1. Patients assessment guided by the nursing process phases			
2. Patients 'reports if these are complete.			

3. Management and treatment techniques			
4.Organisational panning implementation of guidelines			
5.Supervision, mentoring and training of staff			
6. Reporting, assessment of the adverse events.			
7.Strengthen the patient satisfaction surveys			
8.Ensure there is a system to redress the challenges identified in the surveys and clinical audits			
9.Quality improvement projects should be in place so that the problems identified during auditing are addressed			
10.Measures to redress the complains are to be in place and accessible to patients			

Thank you for your valuable participation

Luleka Gcawu (PhD student)

ANNEXURE 8: ROUND TWO DELPHI METHOD QUESTIONNAIRE

DELPHI TECHNIQUE: ROUND TWO

Title: The development of validated guidelines that contribute to the prevention of malpractice litigation in Nursing practice in South Africa.

1 Introduction

A brief overview of the study including results were presented to the participants in round one of the validation process during which the Delphi technique was commenced. After the completion of round one, the draft guidelines, which, the participants were not able to reach consensus on, were revised. A similar questionnaire as applied in round one was completed based only on those guidelines which no consensus was reached.

The rigour of this validation process is supported by experts in the field of quality assurance, specifically quality and safety of patient care. The co-supervisor of this study is an international expert in quality assurance and the supervisor is an expert witness in malpractice litigation with her focus area in quality and safe patient care. Furthermore, the biostatistician, a co-investigator of the main study, has contributed to the face and content validity of the study.

2. Continuation of the Delphi technique, round two

Having agreed to participate in the Delphi technique at the beginning of round one, participants were informed that the process might have more than one round that the process will continue until consensus about the drafted guidelines is reached among participants. Thus, no further informed consent is required.

The purpose of this questionnaire is to request your participation in round two of the validation process of the draft guidelines applying the Delphi technique.

Due to a possible lengthy process, the researcher will appreciate a turnaround time of three (3) days after receiving the questionnaire. The supervisor, co-supervisor or the researcher may be contacted for any queries.

Luleka Gcawu

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Co-supervisor: Prof Stuart Whittaker: Cell: 0834506889 / email: stuart@mqh.co.za

3. Instructions to Delphi validation participants round two

- The questionnaire, which consists of nine (7) pages, will take approximately 45 minutes to complete.
- Please provide your recommendations and comments in the space provided.

SECTION A: DEMOGRAPHIC PROFILE OF DELPHI PARTICIPANT

1. Indicate your professional category

1	Registered Nurse	
2	Registered Medical Doctor	
3	Registered Pharmacist	
4	Other (please specify)	

2. Indicate your highest professional qualification

1	Masters	
2	Doctorate	

3. Indicate your clinical speciality area

1	Medical	
2	Midwifery	
3	Neonatology	
4.	Nephrology	
5	Neurology	
6	Ophthalmology	
7.	Orthopaedics	
8	Paediatrics	
9	Psychology	
10	Surgical	
11	Trauma	
12	Urology	
13	Public health	
14	Obstetrics	
15	Other (specify)	
99	Not applicable	

4. This question may have a multi response answer. Indicate your participation in each area of the following.

1	Academic in healthcare	
2	Consultant in health systems	
3	Participate in accreditation of hospitals	
4	Participating in policymaking in healthcare	
5	Participating in regulating bodies in healthcare	
6	Writing healthcare standards for health establishments	
7	Clinical practice	
8	Other	

SECTION B. CLINICAL MANAGEMENT: PHASES OF THE NURSING PROCESS:

5. PHASE 1 OF THE NURSING PROCESS: SUBJECTIVE INFORMATION

Recommended drafted guidelines	**Agree**	**Disagree**	**Comment**
1.The knowledge about the phases of the nursing process can be assessed by doing a pre-test before in-service training is commenced and a post-test at the end of in-service training	**(1)**	**(2)**	
2. The nurse should verify whether the administration collected the patient 's subjective data (demographic, personal and social data) during assessment namely:			
2.1.Age of the patient			
2.2.Gender			
2.3.Marital status			
2.4. Dependents			

PHASE 1 : OBJECTIVE DATA

Recommended drafted guidelines	Agree (1)	Disagree (2)	Comment
6.The nurse should collect the patient 's objective data during assessment which include vital signs and other tests as listed below depending on the patient's condition and where applicable			
6.(A).The nurse should be able to conduct a physical assessment of the patient which include:			
1. Foot pulse monitoring (When indicated)			
2.Continuous ECG monitoring (in high risk patients)			
3. Monitoring sensation and motor functions of the upper or lower limbs depending on the level of spinal surgery.			
4.Circulation checks post plaster of Paris insertion			
5. Intake (fluids and meals) and output (urine and all types of drainage applicable) monitoring			
6 (B). The routine tests should be done and these form part of assessment:			
1. Haemoglobin			
2.The nurse should be able to conduct a physical assessment of the patient which include:			
1. The professional nurse performing heart and lung auscultation			

7. Phase 5 of the Nursing Process: Evaluation

Recommended drafted guidelines	Agree	Disagree	Comment
If the patient 's condition does not improve the nursing care plans are re-evaluated and re-planned	**(1)**	**(2)**	

SECTION C: HUMAN BEHAVIOURAL PROBLEM

Recommended drafted guidelines	Agree (1)	Disagree (2)	Comment
7. Health care professionals' behavioural problems may be addressed by nursing management as follows:			
1. Encouragement of positive behaviour amongst Health Establishment (HE) managers may contribute to quality care being delivered, reduce absenteeism which is a contributory factor to mismanagement of patients			
2. Establish a strengthened relationship with relevant stakeholders.			

NURSING LEADERSHIP AND MANAGEMENT

Recommended drafted guidelines	AGREE (1)	DISAGREE (2)	Comments
8. Mentoring and coaching should be encouraged by :			
1. Introduction of mentors to coach and support the newly employed nurses and student nurses.			
2. Ensure induction and orientation of newly appointed staff members within the first eight (8) weeks after appointment date.			

9. Continuous nursing professional development (CPD)

Recommended drafted guidelines	**Agree (1)**	**Disagree (2)**	**Comment**
1. Ensure identification of knowledge gaps in each HE by conducting skills audits.			
2. Ensure the development and implementation of a Professional Development Programme.			
3. Refresher course at least six monthly in the Health Establishment on the following:			
1. Anatomy and physiology			
2. Pathophysiology of the most common diseases			
3. Medication indication , contraindications, side effect , effects , action , rout and dosage			
4.Control of drugs			

10. Nursing Monitoring and evaluation: Clinical audits

Recommended drafted guidelines	**Agree (1)**	**Disagree(2)**	**Comment**
10.Conduct clinical audits and check if the following are done as per guidelines, policies and regulations:			
1. Patients 'reports if these are complete.			
2. Management and treatment techniques			

Thank you for your valuable participation

Luleka Gcawu (PhD student)

ANNEXURE 9: VALIDATED GUIDELINES

VALIDATED GUIDELINES THAT CONTRIBUTE TO THE PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE IN SOUTH AFRICA

1. INTRODUCTION

The following validated guidelines were validated using the Delphi method which achieved a consensus level of 90-100% in response to agreeing that they contributed to the prevention of malpractice litigation in Nursing Practice in South Africa.

The guidelines are grouped into the following categories:

CLINICAL MANAGEMENT: The Nursing Process

HUMAN BEHAVIOURAL PROBLEM

ORGANISATIONAL FACTORS

2. CLINICAL MANAGEMENT: THE NURSING PROCESS

2.1. Knowledge and understanding of the phases of the nursing process

VALIDATED GUIDELINE
The nurse should have the required knowledge and understanding of the phases of the nursing process
The knowledge of the phases of the nursing process can be assessed by doing a pre-test before the in-service training is conducted and a post-test at the end of the training.

2.2. Phases of the Nursing Process

2.2.1 Phase 1 Assessment:

2.2.1.1 Subjective data

VALIDATED GUIDELINE
The nurse should collect the patient's subjective data (demographic, personal and social data) during the assessment, namely:
Age of the patient
Gender
Marital status
Dependents

Disability on admission
Social habits which include:
Smoking
Use of alcohol
Use of unsolicited drugs
A comprehensive medical and family history should be done of all patients as stated by the scope of practice for nurses (Nursing Act No. 33 of 2005).

2.2.1.2: Objective data

VALIDATED GUIDELINES
The nurse should collect the patient's objective data during assessment which include vital signs and other special tests as listed below, depending on the patient's condition and where applicable
Blood pressure
Pulse
Temperature
Respiration
Foetal heart monitoring (if applicable)
Foot pulse monitoring (if applicable)
Continuous ECG monitoring (if applicable)
Monitoring sensation and motor functions of upper or lower limbs post spinal surgery (where applicable).
Oxygen saturation (if applicable)
Circulation checks of post plaster of Paris application (if applicable)
Intake and output (if applicable)
Neuro observations (if applicable).
Special investigations should be carried out and these form part of assessment
Haemoglobin
Haemoglucotest
Urinalysis
Weight
Height

The nurse should be able to conduct a physical assessment of the patient which include:
Examination of the body, head-to-toe checking for any abnormalities, bruises, discolouration, disfigurement, pressure sores, and signs of dehydration
The specialist nurse should perform heart and lung auscultation.

2.2.2 Phase 2: Formulating a nursing diagnosis

VALIDATED GUIDELINES
The nurse should be able to analyse all data collected during the assessment phase, interpret it and formulate a nursing diagnosis
Interpret the subjective statements from the patient
Interpret the patient's mental and emotional status
Interpret the data obtained from the physical assessment
To formulate the correct nursing diagnosis the nurse should understand the following:
Normal and abnormal ranges of the vital signs
Normal and abnormal ranges of the tests that are done on the patients
Interpret the data obtained from the physical assessment
Normal and abnormal ranges of the special tests done

2.2.3 Phase 3: Planning

VALIDATED GUIDELINES
The nurse should understand how to formulate nursing interventions and outcomes as follows:
The nursing care plans should be set such that they are achievable and measurable
The nurse should set long and short term goals and each goal should have an expected outcome
The special care plans are also formulated during this stage where required
The nursing care plans should be written clearly on the patient's nursing process records so that they are accessible to other health professionals.

2.2.4 Phase 4: Implementation

VALIDATED GUIDELINES
The care plans are implemented in this stage. The nurse should note the following:
Conducting nursing care activities and these should be guided by the availability of skills, knowledge and scope of practice
Patient treatment techniques that were prescribed in phase 3 are executed in this stage
Adhering to protocols, guidelines and standards that are laid down by the institution, governing body and employer.

2.2.5 Phase 5: Evaluation

VALIDATED GUIDELINES
This is a stage where a nurse continuously evaluates the effectiveness of the nursing care activities documented in the implementation and planning stages. The nurse should note the following:
Modify the care plan as needed.
If the patient ‘s condition does not improve the nursing care plans are re-evaluated and re-planned
VALIDATED GUIDELINES
2.3 Documentation
2.3.1 Documentation for continuity of care **Documentation should be done in all stages of the nursing process to ensure continuity of care. The nurse should note the following:**
Documentation should meet the acceptable principals of documentation
Clear documentation that is precise to the point
Date and time should always appear in the patient’s records
Correction ink should not be used in patients’ documents
Signature and designation of the person that was documenting should be clear
2.3.2 Reports
The patient’s report should be written completely which follows the stages of the nursing process that include:
Initial report
Progress reports
Interim reports
Transfer reports
Crisis report

Death report
Discharge report
Discharge reports should indicate patient education given.

3 HUMAN BEHAVIOURAL PROBLEM

VALIDATED GUIDELINES
Healthcare professionals' behavioural problems should be addressed by nursing management as follows:
Ensure that a HE nursing philosophy is in place which is discussed periodically for reinforcement
Encourage good moral behaviour amongst the nurses
Ensure that there is openness, transparency, honesty and professional values amongst the healthcare professionals in the HE
Ensure that there is continuous staff motivation so that staff demotivation is reduced
Introduce a just culture environment in the HE to promote the need for an open and honest reporting system within a quality learning environment
Attend to the factors that may negatively affect the staff behaviours such as staff shortage, work overload, favouritism, compulsory overtime and conflicts
Introduce an environment that is nonpunitive but corrective
Ensure that there is a culture of trust, reporting, transparency and discipline
Introduce and implement disciplinary measures where it is necessary
Introduce a grievance procedure
Introduce a performance appraisal programme to award the best performing staff members
Establish and strengthen debriefing centres in the HE such as staff counselling centres, Employee Assistant Programmes, clinical psychology and team-building committees
Conduct climate meetings whereby each staff member will feel free to voice without fear, concerns without fear of discrimination and victimisation. This environment should be well protected and professional.
Establish a strengthened relationship with relevant stakeholders.

4. ORGANISATIONAL FACTORS

Validated guidelines
4.1. Leadership and management
The health establishment (HE) should ensure that there are effective leadership, active collaboration and good governance by:
Ensure that the vision and mission statement gives guidance to service delivery
Ensure that the quality assurance department and in-service education departments work together to identify and address the knowledge gaps
Establish committees such as a quality assurance committee, research committee, in-service education committee, budget committee, health and safety committee, skills development committee and audit committee. Each department should be represented
Ensure that the committees are resourced and functional
Ensure that there are proper planning and organisation in the HE that can contribute to the prevention of substandard care
Develop strategic plans that will guide the nursing care activities
Ensure that there are proper staffing norms and the staff is allocated according to the needs of each department
Prioritising adequate human and material resources
Implementing effective recruitment and retention strategies
Allocate budget allocation for the needs of the HE
Developing and implementing structure standards, process standards and outcome standards
Implementing the patients' rights charter whereby patients' rights are respected and not violated in the HE
Ensure that there is an infection control department
Ensure that the disaster management plan is in place
Ensure that a risk management plan is in place and staff is knowledgeable on how to manage and analyse risk.
Ensure that an effective communication system, whereby patients and staff members are well informed should be in place
Ensure that the facilities and infrastructure are maintained to meet the applicable regulations
Management skills and styles that need to be properly explored to avoid selecting managers who lack management skills, as this may lead to poor management and substandard care being provided in HE

Implementing a multidisciplinary approach to ensure an efficient and effective HE organisation
4.2. Mentoring and coaching
Ensure increased continuous mentoring and coaching within the work environment will increase job security
Provide mentoring, coaching and supervision in a non-threatening, noninterfering manner
Introduce mentors to coach and support the newly employed nurses and student nurses
Ensure the induction and orientation of newly appointed staff members within the first eight (8) weeks after appointment date.

Validated guidelines
4.3. Operational management: **The wards / units in the HE should ensure that there is implementation of operational plans and this can be done by ensuring that:**
Institutional plans are implemented and the unit operational plans are in line with those of the HE
There is an adequate supply of equipment and in good working order
The measures to control infection are in place and the staff is well informed about these measures
Stock supply and control is done
Management techniques are implemented
There is unit team building
There is staff development
Proper organisation and planning
There are proper work allocation and distribution of work according to the scope of practices
Patient safety measures are in place such as infection control measures and cleanliness.
The operational standards are implemented guided by guidelines, policies, acts and regulations
Management by objectives, in-service training and clinical demonstrations can be used as unit/ ward measures for staff development
A conflict management programme is in place

4.4. Continuous nursing professional development (CPD)

Validated guidelines
Identify knowledge gaps in each HE by conducting small surveys and clinical audits
Encourage staff members to identify the areas they do not feel competent in
Introduce a scheduled programme for in-service and informal training at the hospital level
Identify topics that will be offered weekly basis and those that will be offered on 6-month intervals
Informal training can be implemented by making use of the morning meeting session, using posters and pictures to engage all learning strategies
Prioritise the topics that have to be included in the HE in-service education programme based on the identified needs
Staff members to attend seminars, conferences and workshops
Encourage staff members to register for formal education at colleges and universities
Incorporate adverse events and malpractice litigation in the curricula of Nursing Education institutions
Identified knowledge gaps should be bridged by doing refresher courses
In-service education department should ensure implementation of the in-service education programmes
Refresher course of at least six months in the Health Establishment based on the conditions of a particular unit/ ward. The following should be included:
Anatomy and physiology
Pathophysiology of the most common diseases of patients admitted to the ward/unit
Management of pathological conditions
Medication indication, contraindications, side effects, effects , actions, route and dosage
Control of drugs
Establish opportunities where nursing personnel can be made aware of the adverse events, as well as the near misses within the organisation and how these gaps are negatively affecting the quality and safety of patient care
The nurses should be given in-service education on how to prevent adverse events, analyse and write reports on adverse events.

4.5. Nursing monitoring and evaluation

Validated guidelines
Conduct clinical audits and check if the following are done according to guidelines, policies and regulations:
Patients' assessment guided by the nursing process phases
Patients' reports if these are complete
Management and treatment techniques
Organisational planning and implementation of guidelines
Supervision, mentoring and training of staff
Reporting and assessment of the adverse events
Strengthening the patient satisfaction surveys
A system to redress the challenges identified in the surveys and clinical audits
Quality improvement projects are in place to identify problems during auditing
Measures to redress the complaints in place and accessible to patients

ANNEXURE 10: LANGUAGE EDITOR CERTIFICATE

Lona's Language Services

English/Afrikaans
Afrikaans/English

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* Translations * Editing * Proofreading
* Transcription of Historical Docs
* Transcription of Qualitative Research
* Preparation of Website Articles

TO WHOM IT MAY CONCERN

This letter serves to confirm that the undersigned

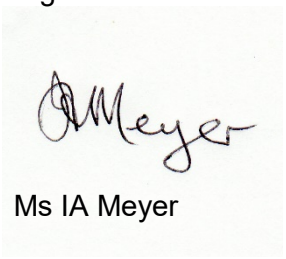
ILLONA ALTHAEA MEYER

has edited and proofread the **doctoral thesis of Luleka Gcawu** for language correctness and

translated the Abstract.

TITLE: THE DEVELOPMENT OF VALIDATED GUIDELINES THAT CONTRIBUTE TO THE PREVENTION OF MALPRACTICE LITIGATION IN NURSING PRACTICE IN SOUTH AFRICA

Signed



Ms IA Meyer

03 October 2019

ANNEXURE 11: CERTIFICATE OF TECHNICAL FORMATTING COMPLETED

Lize.net
COMMUNICATION (Pty) Ltd
Company registration: 2019/050723/07

To whom it may concern

This letter serves as confirmation that I, Lize Vorster, performed the language editing and technical formatting of Luleka Patricia Gcawu's thesis entitled:

The development of validated guidelines that contribute to the prevention of malpractice litigation in nursing practice in South Africa

Editing is done in track changes and the student has final control over accepting or rejecting changes at their own discretion. Technical formatting entails complying with the Stellenbosch University's technical requirements for theses and dissertations, as presented in the Calendar Part 1 – General or where relevant, the requirements of the department.

Yours sincerely

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Language Practitioner

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